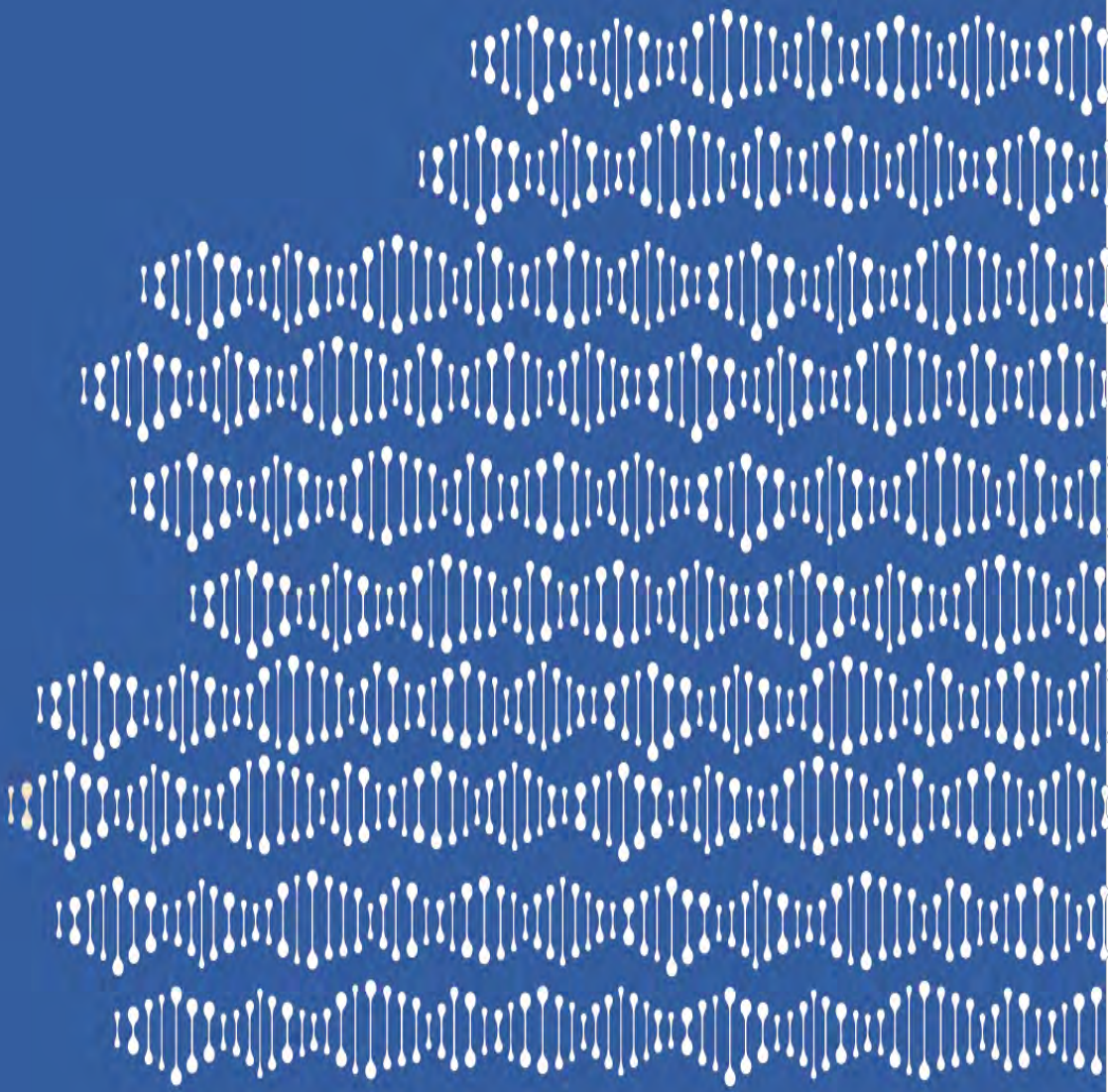
CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Oversight Committee Meeting

May 18, 2016



CANCER PREVENTION & RESEARCH
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Summary Overview of the May 18, 2016, Oversight Committee Meeting

This summary provides an overview of major agenda items and background on key issues for Committee consideration at the May 18, 2016, Oversight Committee meeting.

CEO Report
Wayne Roberts will present the CEO's report and address issues including a personnel update, action items from the February 17 Oversight Committee meeting, the 2016 customer survey, and a report on the grant funds available for FY 2016..

Chief Scientific Officer Report and Grant Award Recommendations
Dr. James Willson will provide an update on the Academic Research Program and present the Program Integration Committee's award recommendations for Core Facilities, High-Impact High-Risk, Multi Investigator, and First-Time, Tenure-Track Faculty recruiment grants.

Information related to the Academic Research grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Product Development Officer Report
Michael Lang will provide a Product Development Research Program update and present the Program Integration Committee's award recommendations for New Company Product Development Research grants.

Information related to the Product Development Research grant applications recommended for funding is not publicly disclosed until the Oversight Committee meeting. The information is available to board members through a secure electronic portal.

Chief Prevention and Communications Officer Report
Dr. Becky Garcia will give a report regarding the Prevention Program activities as well as an update on the agency's communications activities.

Scientific Research and Prevention Programs Committee Appointments
The Chief Executive Officer has provisionally appointed 15 new members to CPRIT's Scientific Research and Prevention Programs Committees. CPRIT's statute requires the Oversight Committee to approve the CEO's recommendations before the appointment is final. Biographical sketches for the appointees are included in the board packet.

Health and Safety Code 102.1062 Waiver
Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation" provides a process for the Oversight Committee to consider and approve a waiver of statutory

conflicts of interest for individuals involved in the grant review or award process. Mr. Roberts proposes a waiver for Dr. Becky Garcia, CPRIT's Chief Prevention Officer. In order to approve the waiver, the Oversight Committee must find that exceptional circumstances justify the conflicted individual's participation in the review process. The proposed waiver includes limitations and other protections in place to mitigate the opportunity for the award of grant funds to be affected by anything other than merit and established criteria.

Chief Operating Officer Report
Heidi McConnell will discuss the operating budget, performance measures, and debt issuance history for the second quarter of FY 2016. Ms. McConnell will also present drafts of two required reports, CPRIT's Strategic Plan and the agency's Legislative Appropriations Request. These reports set the stage for the upcoming legislative session. Both reports will be due before the August Oversight Committee meeting, so Ms. McConnell will present a plan for provisional approval by the Oversight Committee.

Grant Management Support Services Contract
Ms. McConnell will present a recommendation for provisional approval of a $10 million grant management services contract. Because of its potential value, the request for proposals (RFP) has been reviewed via the interagency Contract Advisory Team Review and Delegation process. The RFP is currently open through mid-June.

FY 2017 Bond Issuance Resolution
The Texas Public Finance Authority (TPFA) is statutorily authorized to issue debt on behalf of CPRIT. The Oversight Committee will consider a resolution requesting financing for $300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards.

Chief Compliance Officer Report
Vince Burgess will report on the status of required grantee reports, financial status report reviews, annual grantee certifications, desk reviews and site visits as well as grantee training and technical assistance.

Compliance Support Services Contract
CPRIT's contract with CohnReznick allows the agency to exercise its one-year renewal option. Mr. Burgess will present the recommendation to extend the contract for compliance monitoring services in FY 2017.

Internal Auditor Report
Weaver and Tidwell, CPRIT's internal auditor, will provide a status report on CPRIT's outsourced internal audit services.

Final Order Approving Amendments to 25 T.A.C. Chapters 702 and 703
Ms. Doyle will summarize the comment received about the proposed rule changes initially presented to the Oversight Committee in February. The rule amendments will become effective

20 days after filing the final order with the Secretary of State. The rule amendments include the following:

- § 702.11: clarifies that a professional conflict of interest includes serving as a consultant or contractor for a grant applicant
- § 703.12: prohibits reimbursement of visa fees
- § 703.21: Adds an appeal process if the grantee's reimbursement of project costs is waived by operation of law

Subcommittee Business

Mr. Roberts and Dr. Cynthia Mulrow will present the Diversity Subcommittee's recommendation to consider transferring the responsibilities of the Diversity Subcommittee to other standing subcommittees. Feedback will be considered and a final recommendation is expected in August.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Agenda

Texas State Capitol Extension
1400 N. Congress Avenue, Austin, Texas 78701
Room E1.012

May 18, 2016
10:00 a.m.

The Oversight Committee may discuss or take action regarding any item on this agenda, and as authorized by the Texas Open Meetings Act, Texas Government Code Section 551.001 et seq., may meet in closed session concerning any purposes permitted by the Act. Anyone wishing to offer public comments must notify the Chief Executive Officer in writing prior to the start of the meeting. The Committee may limit the time a member of the public may speak.

1. Call to Order
2. Roll Call/Excused Absences
3. Adoption of Minutes from the February 17, 2016, meeting **TAB 1**
4. Public Comment
5. Chief Executive Officer Report **TAB 2**
   - FY 2016 Proposed Grant Awards Budget and Programmatic Funding Targets
6. Chief Scientific Officer Report and Grant Award Recommendations **TAB 3**
7. Chief Product Development Officer Report and Grant Award Recommendations **TAB 4**
8. Chief Prevention and Communications Officer Report **TAB 5**
9. Scientific Research and Prevention Program Committee Appointments **TAB 6**
10. Health & Safety Code Section 102.1062 Waiver **TAB 7**
11. Chief Operating Officer Report **TAB 8**
    - State Agency Strategic Plan 2017 – 2021
    - Legislative Appropriations Request for 2018 – 2019 biennium
12. Grant Management Support Services Contract **TAB 9**
13. FY 2017 Bond Issuance Resolution **TAB 10**
14. Chief Compliance Officer Report **TAB 11**
15. Compliance Support Services Contract **TAB 12**
16. Internal Auditor Report **TAB 13**
17. Final Orders Approving Amendments to 25 T.A.C. Chapters 702 and 703 **TAB 14**
18. Personnel – Chief Executive Officer
19. Subcommittee Business **TAB 15**
20. Compliance Investigation Pursuant to Health & Safety Code § 102.2631
21. Consultation with General Counsel
22. Future Meeting Dates and Agenda Items
23. Adjourn

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Oversight Committee Meeting Minutes

February 17, 2016

1. Meeting Called to Order

A quorum being present, Presiding Officer Geren, called the Oversight Committee to order at 9:06 a.m.

2. Roll Call /Excused Absences

Board Members Present:
Angelos Angelou
Donald (Dee) Margo
Pete Geren
Ned Holmes
Will Montgomery
Cynthia Mulrow, M.D.
Amy Mitchell
Bill Rice, M.D.
Craig Rosenfeld, M.D.

3. Adoption of Minutes from the November 19, 2015, Oversight Committee Meeting (TAB 1)

MOTION:
Presiding Officer Geren called for a motion to approve the minutes of the November 19, 2015, Oversight Committee meeting.

Motion made by Dr. Rosenfeld and seconded by Mr. Montgomery.
MOTION CARRIED UNANIMOUSLY

4. Public Comment

Presiding Officer Geren stated there were no requests for public comment.

5. Chief Executive Officer Report (TAB 2)

Mr. Wayne Roberts, Chief Executive Officer, introduced Dr. James Willson, the new Chief Scientific Officer, whose start date will be March 1, 2016.

Staff has begun collecting data related to recruitment awards, including the number of full-

time employees (FTEs) added with each recruitment award, additional funding (and grants) brought to Texas, and post-grant developments. Mr. Roberts stated the Oversight Committee will hear more about this project.

Mr. Roberts stated that Texas Health and Safety Code § 102.260(c) requires the Chief Executive Officer to report at least annually to the Oversight Committee on the progress and continued merit of each program. He reported that CPRITs Academic Research Program, Prevention Program, and Product Development Research Program each showed progress and merit in fiscal year 2015, with further details in the Oversight Committee meeting materials.

Mr. Roberts noted the Oversight Committee requested at its November 19, 2015, meeting that staff provide information on options for ensuring compliance with Texas Health and Safety Code § 102.203(e), which limits to 10% the amount of grant funding that may be obligated for cancer prevention grants each year. Currently, Prevention Program grants awarded by CPRIT exceeds the statutory limit by $2.77 million. This inconsistency can be attributed to three factors, which cause CPRIT to exceed its 10% limit: 1) research program grants being declined after the fiscal year end; 2) increases in the operating budget to support additional grant award processes; and 3) Oversight Committee approval of prevention grants prior to the moratorium that stopped consideration of grant recommendations in other programs for the remainder of fiscal year 2013.

To comply with the statutory directive and resolve the remaining overage, Mr. Roberts presented for the Oversight Committee's consideration three options identified by CPRIT staff to realign prevention grant spending.

Option 1 is a realignment of funding by a one-time reduction of $2.77 million in fiscal year 2017. This approach would have the disadvantage of slowing the momentum CPRIT has gained following the fiscal year 2013 moratorium. However, this option means that CPRIT remains out of compliance until 2017.

Option 2 is an incremental realignment, spreading the $2.77 million across the next several years. This approach minimizes the impact on future Prevention projects and allows more time for a natural resolution of the overage as Prevention grantees do not expend the full amount obligated by contracts ending in a given fiscal year. The disadvantage is that CPRIT does not fully resolve the noncompliance issue for several years.

Option 3 is a retroactive realignment by contract and fiscal year amending active fiscal year 2013 through fiscal year 2016 prevention contracts to reduce funding awarded in each fiscal year so that the total prevention funding would equal 10% of the total grant funds awarded in all programs each fiscal year. This option addresses the issue immediately but would significantly disrupt grantee budgets.

Mr. Roberts introduced Ms. Ramona Magid, Senior Program Manager for Prevention, to represent Dr. Rebecca Garcia, Chief Prevention and Communications Officer, who was unable to attend the meeting.

Mr. Roberts was asked if he had a recommendation for the Oversight Committee. Mr. Roberts stated Dr. Garcia's preference would be to have the reduction taken in fiscal year 2019, with the assumption that over time there would be a natural resolution of the overage as Prevention grantees do not expend the full amount obligated by contracts. Mr. Roberts stated that he recommended taking the amount from fiscal year 2017 to demonstrate that the agency took corrective action as soon as the issue was discovered. He feels taking the reduction in 2016 would be too disruptive, but taking the reduction in 2017 would show good intent on behalf of the agency. An Oversight Committee member asked about the wording in the statute regarding the 10% requirement. Mr. Roberts responded that the statute directs CPRIT to adhere to the 10% maximum each year and not at the end of CPRIT's grant process.

An Oversight Committee member asked about the effect of a reduction in 2016. Ms. Magid stated she and Dr. Garcia had worked to restore momentum of the program after the moratorium and that as a result there were currently 35 grant applications in response to Requests for Applications that will close March 3, 2016. This is higher who compared to the previous cycle with 12 starts. She stated that $14 million is available to fund prevention grants for the balance of fiscal year 2016, and taking the full amount in 2016 would be a reduction of $2.77 million. An Oversight Committee member noted that it would not affect grants already approved for 2016, but would affect only grants not yet approved for 2016.

An Oversight Committee member asked if the Prevention Program's goal to cover the majority of the state with prevention grants would be impacted by taking the full reduction in the remaining cycle of 2016. Ms. Magid said that it could affect that goal.

Another Oversight Committee member noted that the majority of research grant funding by CPRIT has been along the IH35 corridor, but prevention grants tend to include rural West Texas and Border areas.

Another Oversight Committee member pointed out that if all historical grants were taken into consideration instead of only active grants, there would be only two counties (Coryell and Hopkins, covering a total population of approximately 100,000), which never have been covered by prevention grants.

In response to an Oversight Committee member question about recent efforts to inform people about CPRIT funding opportunities, Ms. Magid stated that she and Dr. Garcia made several trips into areas of the state that had no or few projects serving them. As a result, some that were visited have started grant applications.

Presiding Officer Geren proposed that the committee approve a "one-third/two-thirds" approach to the $2.77 million reduction; taking one-third in the remaining part of fiscal year 2016, one-third in the first half of fiscal year 2017, and one-third in the second half of fiscal year 2017. He stated this would show good faith and spread out the reduction over a period of time.

In a response to questions about the possible response from the Legislature to CPRIT being out of compliance and the agency's attempts to resolve the issue, Presiding Officer Geren stated there is no strict legal guidance to handle this matter. He asked Ms. Kristen Doyle, CPRIT General Counsel, what discretion an agency's governing body has under administrative law to remedy a failure to comply with statutes. Ms. Doyle stated that the non-compliance is an inadvertent violation caused mainly by declinations of research grant awards. By its actions, CPRIT has attempted to be fully compliant, but when declinations come after the close of a fiscal year it affects the denominator for setting a 10% target. There is no specific guidance in statute to address the agency's actions once an overage has been identified. The Oversight Committee taking action to identify and correct the problem as soon as possible communicates the agency's desire to address the problem as well as balancing the Prevention Program priorities.

Staff presented several actions to ensure this doesn't continue to be an issue including awarding less than 10% per year in the Prevention Program to address the possible declinations in other programs after the fiscal year. An Oversight Committee member confirmed with Ms. Doyle that the 10% is a statutory maximum, not an amount that must be achieved. She stated that since it is a maximum, the agency may award less.

Presiding Officer Geren confirmed with Ms. Doyle that it is her opinion that any of the approaches suggested would be consistent with the agency's legal obligations.

Presiding Officer Geren called for a motion to realign the Prevention Program funding to comply with Texas Health & Safety Code § 102.203 by taking one-third of the overage out of the second half of fiscal year 2016 and two-thirds of the overage out of fiscal year 2017 so that the total overage amount will be recouped in those two fiscal years.

An Oversight Committee member asked if, after March 3, 2016, applications in the areas not currently covered by CPRIT grants are not received, can the amount taken from 2016 be increased and the amount from 2017 accordingly decreased. Ms. Doyle stated that the motion as crafted will allow the Chief Operating Officer to determine the amount to be reduced in each year, which will allow for any changes in the applications received.

MOTION:

Presiding Officer Geren called for a motion to realign the Prevention Program funding to comply with Texas Health & Safety Code § 102.203 by taking one-third of the overage out of the second half of fiscal year 2016 and two-thirds of the overage out of fiscal year 2017 so that the total overage amount will recoup in those two fiscal years.

Motion made by Mr. Holmes and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

Request to Amend Minutes of September 10, 2105, meeting

Mr. Roberts presented a request to amend the minutes of the September 10, 2015, meeting to reflect that Mr. Angelou voted to approve an award to The University of Texas at Austin (RR160005) at a time when he held a conflict of interest because of his work with the athletics department of the university. Mr. Angelou self-reported the conflict after becoming aware of the issue and conferring with CPRIT's general counsel. It was determined his work with the university had nothing to do with cancer research or prevention and did not involve anyone applying to receive CPRIT grants. Mr. Angelou's vote did not affect the outcome of the recommendation, which received unanimous approval by the Oversight Committee.

MOTION:

Presiding Officer Geren called for a motion to add an addendum to the minutes for the September 10, 2015, meeting to reflect that Mr. Angelou had a conflict of interest with award RR160005 that he inadvertently failed to report and has now brought the conflict to the attention of the Oversight Committee.

Motion made by Mr. Montgomery and seconded by Ms. Mitchell.

MOTION CARRIED UNANIMOUSLY

Funding targets for fiscal year 2016

Mr. Roberts discussed the projected funding available for the remainder of fiscal year 2016. To date there was $72.06 million available for both academic research and product development research awards, and $14.7 million for prevention awards. The $72.06 million will increase slightly due to the decision earlier in this meeting on the Prevention Program funding but not significantly enough to affect this funding target discussion.

At the Oversight Committee meeting in November 2015, staff was instructed to begin the discussion on setting targets for funding between the three programs. As applications for funding continue to increase, it is possible that recommendations from the review panels might exceed available monies. The Oversight Committee will need to meet to begin a discussion among the committee members and agency staff where various permanent approaches could be proposed and reasoned through. Currently, staff estimates there is enough funding for the awards anticipated to be approved by the Oversight Committee in May 2016; however, these estimates do not include any additional recruitment applications, which could result in more proposed awards than available funding. Mr. Roberts recommended a two-prong approach to target setting which would include a temporary target for the remainder of fiscal year 2016, and a more in-depth discussion to set a permanent target for following fiscal years. The meeting materials contain options for the remainder of fiscal year 2016. Mr. Roberts stated that staff would know the amount of funding needed by the May 2016 meeting. Mr. Roberts recommended that CPRIT assertively move forward with establishing funding target guidance for fiscal year 2017 and beyond.

An Oversight Committee member asked about the status of the expected overage in Academic Research proposed awards. Mr. Roberts responded that there is sufficient funding for the $70.3 million in awards that Dr. Margaret Kripke, Chief Scientific Officer, is

projecting, based upon a historical evaluation of the request for applications (RFAs) that are coming forward. That projection does not take into account additional recruitment recommendations that could occur. Mr. Roberts suggested that Dr. Kripke work with the Scientific Review Council to more accurately predict the funding needed. An Oversight Committee member asked if the RFAs are issued with a cap on the award amount. Dr. Kripke stated the RFAs do have a cap. The current round of RFAs include core facilities awards, high-impact high-risk awards, and multi-investigator research awards. They each have a different cap. The high-impact high-risk awards are limited to $200,000 over a two year period—very small amounts that she does not recommend reducing. A multi-investigator award could be several million dollars, with a cap of $1.5 million per year and $7.5 million over a five year period. She stated the total amount of the proposed awards will not be known until after the Scientific Review Council meeting. The core facility awards are capped at $6 million over a five year period. Therefore, it is likely that funding must be limited; one or more of the very large awards could be deferred to the August 2016 Oversight Committee meeting.

An Oversight Committee member requested clarification on whether the caps are on individual awards or on aggregate funding of awards. Dr. Kripke stated that the cap is on aggregate funding and is the amount available for spending on programmatic issues. Until recently, there was no need to prioritize which grants would receive funding because there was enough funding to approve all grants recommended by the Scientific Review Council. Mr. Roberts added that the Scientific Review Council is asked to rank the projects, then the Program Integration Committee (PIC) is charged with culling the awards to meet the funding available, if necessary. If the PIC is unable to prioritize sufficiently, ultimately, the final authority is with the Oversight Committee. He also stated that it is preferred that the prioritization take place at the Review Council level since they are the science experts, though each Review Council can only take into account their own program when prioritizing.

Mr. Roberts confirmed for an Oversight Committee member that the funding for the Academic Research and Program Development Research program grants come from the same allocation which means if more funds are expended for Academic Research, less will be spent on Product Development Research.

Presiding Officer Geren noted that guidelines given to staff on how to prioritize and allocate those funds is one of the important decisions the Oversight Committee must make. For the May meeting, the Oversight Committee needs to give the staff guidance on how to prioritize the grants for the remainder of fiscal year 2016. At a special workshop meeting, the Oversight Committee will consider more fully the options for guidance in future years.

In response to an Oversight Committee member question about possibly deferring award approvals to a September 2016 meeting, Ms. Doyle stated that awards can be deferred only in the fiscal year in which they are recommended, which ends August 31. If an award is to be deferred to the next fiscal year, the Review Council would need to defer their recommendation.

An Oversight Committee member asked if product development research awards had caps and if the Product Development Review Council considered the amount of the application in any way. Ms. Doyle responded that there is a $20 million cap on product development research awards and the Product Development Review Council does look at the amounts being requested. She stated the cap is a CPRIT operational cap, not a statutory cap. While there is normally a restriction on communications between the Chief Product Development Officer and potential grantees, the Chief Executive Officer may grant an exception to that restriction to allow staff to have budget discussions with applicants before the May meeting to determine if their budgets could be adjusted to stay within available funding.

An Oversight Committee member asked if a choice had to be made between a core facility award and a multi-investigator award, which would be chosen. Dr. Kripke responded it would depend more on whether the application was coming from an institution that had not received significant CPRIT funds, as a less funded institution would most likely receive priority. Mr. Roberts added that the Oversight Committee's program priorities would also be considered when recommending an award. Both of these considerations occur prior to weighing a core facility versus a multi-investigator award.

Another Oversight Committee member inquired why an award recommendation cannot be carried over to the next fiscal year. Ms. Doyle responded that it is a statutory requirement that the recommendation be acted upon within the fiscal year the review council makes the recommendation. Legally, staff can give direction to a review council and this has happened with recruitment awards and product development research awards to ensure sufficient funding is available. Dr. Kripke commented that deferring grants can also require them to be updated and the process becomes complicated, along with taking available funds from the next fiscal year.

An Oversight Committee member asked for confirmation that over the next year the committee will consider whether to allocate more funding to Product Development Research awards that would otherwise have gone to Academic Research awards. Presiding Officer Geren stated that, in order to provide guidance to staff, the Oversight Committee would consider funding targets more broadly than just whether current funding for product development research is the appropriate amount and will include how CPRIT policies can best serve the people of Texas.

Presiding Officer Geren noted Mr. Roberts' recommendation that the Oversight Committee meet in a workshop session in May to discuss funding targets.

6. Chief Scientific Officer Report and Grant Award Recommendations(TAB 3)

Dr. Margaret Kripke, Chief Scientific Officer reported on the activities of the Academic Research Program:

- Academic Research Grants Currently Under Review
  - 208 applications received

- New Requests for Applications (RFAs)
    - Academic Research request for applications will be posted February 19, 2016 and will be due by May 19, 2106, to be brought before the Oversight Committee at their November 2016 meeting.

Proposed Academic Research Grant Awards

Presiding Officer Geren noted that the grant award recommendations were in the meeting materials handout titled "Proposed Grant Awards."

Dr. Kripke reported that 12 applications went before the Scientific Review Council and eight were recommended to the Program Integration Committee (PIC). Of those eight, two (RR160028 and RR160030) declined the recruitment offers after the PIC had acted. Therefore, six awards are presented for approval by the Oversight Committee: three established investigator awards, one rising star award, and two first-time faculty awards. Total award funding being requested for recruits is $26 million. One of the first-time faculty awards and one of the established investigator awards are in computational biology, addressing a program priority set by the Oversight Committee.

An Oversight Committee member asked if Dr. Kripke felt there should be any priority for attracting outstanding researchers to a new medical school, as opposed to an established facility with large departments. Dr. Kripke said no consideration has been given to whether the recruits were going to established or new facilities, though some candidates are faculty recruitments for the new medical school at The University of Texas at Austin.

Academic Research Grant Award Recommendations

REC 16.4				
App ID	**Candidate**	**Mechanism**	**Organization**	**Budget Request**
RR160029	Xiaodong Cheng	Recruitment of Established Investigators	The University of Texas M. D. Anderson Cancer Center	$6,000,000
RR160023	Daniel Leahy	Recruitment of Established Investigators	The University of Texas at Austin	$6,000,000
RR160027	Bing Zhang	Recruitment of Rising Stars	Baylor College of Medicine	$4,000,000

*Note: Grant applicant RR160028 withdrew after the Program Integration Committee met.

REC 16.5-6				
App ID	**Candidate**	**Mechanism**	**Organization**	**Budget Request**
RR160034	Luke Andrew Gilbert	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas Southwestern Medical Center	$2,000,000
RR160031	Filippo G. Giancotti	Recruitment of Established Investigators	The University of Texas M. D. Anderson Cancer Center	$6,000,000
RR160032	Traver Hart	Recruitment of First-Time, Tenure-Track Faculty Members	The University of Texas M. D. Anderson Cancer Center	$2,000,000

*Note: Grant applicant RR160030 withdrew after the Program Integration Committee met.

COMPLIANCE CERTIFICATION

Mr. Vince Burgess, Chief Compliance Officer, presented his report on the review process for the grant awards being recommended to the Oversight Committee. He noted that two applications were withdrawn, RR160028 and RR160030, after he submitted his report in the meeting materials. He certified that recommended awards complied with applicable statutory and administrative requirements for the three academic recruitment award slates being presented for approval at this meeting.

CONFLICT OF INTEREST NOTIFICATIONS

Presiding Officer Geren noted that Mr. Angelou had reported a conflict of interest with application RR160023 submitted by The University of Texas at Austin.

MOTION:

Presiding Officer Geren called for a motion to approve the Program Integration Committee recommendation for a recruitment grant to The University of Texas at Austin, RR160023.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

Presiding Officer Geren noted for the record that Mr. Angelou abstained from voting.

MOTION:

Presiding Officer Geren called for a motion to approve the Program Integration Committee's recommendations for recruitment grant awards to The University of Texas

M.D. Anderson Cancer Center, The University of Texas Southwestern Medical Center and the Baylor College of Medicine.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

Presiding Officer Geren noted for the record that the Oversight Committee did not consider RR160028 and RR160030 because the applications were withdrawn.

MOTION:

Presiding Officer Geren entertained a motion to delegate contract negotiation authority to the Chief Executive Officer and CPRIT staff, and to authorize the Chief Executive Officer to sign the contracts on behalf of CPRIT.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

7. Chief Prevention and Communications Officer Report (TAB 4)

Presiding Officer Geren called on Ramona Magid, Senior Program Manager for Prevention to present for Dr. Rebecca Garcia, Chief Prevention and Communications Officer, who was unable to attend.

Prevention Program

Ms. Magid reported:

- 11 awards are currently going through the contract process.
- Applications for FY2016 Cycle 2 are due on March 3, 2016.
- Staff traveled to the Rio Grande Valley to meet with various representatives of a new medical school, local hospitals and clinics, and a CPRIT grantee.

Ms. Magid reported that in addition to the impact on the health of the people in Texas, prevention grants impact the healthcare system by fostering greater collaborations, reducing wait times for diagnostic testing, reducing the number of people lost to follow-up, implementing patient reminder systems, enhancing electronic medical records, and training community health care workers to educate and navigate people through the medical system.

Communications

Mr. Roberts stated that Dr. Garcia's Communications report was in the meeting materials but that Dr. Garcia would like to call specific attention to the comments regarding the CPRIT Innovations in Cancer Prevention and Research Conference held in November 2015. He noted that 823 people registered for the conference. According to the survey,

in terms of the location for future conferences, 39% preferred Austin, 24% Houston, 18% San Antonio, and 17% Dallas. The projected actual revenue for the conference is $245,950 and the projected actual expenses are $227,748, making the net revenue collected from the conference projected to be approximately $18,000 which will be available for the next conference.

8. Chief Product Development Officer Report (TAB 5)

Mr. Michael Lang, Chief Product Development Officer, reported on the activities of the Product Development program, including:

- Product Development Research Application Review Process Updates
- Product Development Review Council (PDRC) Membership
- Early Translational Research Awards (ETRA) – Business Plan Review
- Company Connections and other Activities of the Chief Product Development Officer
- Product Development Research Program Strategy
- Equity Ownership Policy
- Company Specific Issues

Mr. Lang stated that at their last meeting on November 19, 2015, the Oversight Committee approved a $20 million grant award to Ruga Corporation (Ruga) subject to three contingencies. Ruga has successfully addressed those contract contingencies. However, after conferring with the Product Development Review Council, Mr. Lang stated it is his opinion that the requirement related to hiring a new Chief Executive Officer is no longer necessary as the company has had a Chief Executive Officer for over two years who is a medical doctor with the appropriate background for the position. After discussion with company representatives and a detailed analysis of the license agreement, he stated that he is satisfied that the 15% royalty rate is applicable only in the event that Ruga sublicenses the technology, is typical of drug industry licensing, and unlikely to be an impediment to future funding. Another concern was that a manufacturing company might ask for an additional royalty, which was successfully addressed by having several company options that will not be able to request a secondary royalty. A third concern was location of the Ruga team, which is currently in San Francisco. The current management team has committed to relocate to Texas upon approval of the award and all new hires will be based in Texas.

Mr. Lang recommended the Oversight Committee delegate authority to CPRIT's Chief Executive Officer to execute the award contract with Ruga Corporation that does not include a contingency requiring hiring of a new Chief Executive Officer (CEO) for Ruga. Mr. Lang stated that, while the primary investigator did function briefly as the CEO, Ruga has had a qualified CEO in place for a couple of years now.

Dr. Geren noted that the Ruga contract and contingencies were discussed at the February 11, 2016, Product Development Subcommittee meeting and the subcommittee recommends approval.

An Oversight Committee member asked for clarification and confirmation that under no circumstances will any manufacturing company have a royalty. Mr. Lang stated that Ruga's Chief Executive Officer has affirmed that no manufacturing company will be afforded a royalty.

Another Oversight Committee member asked about the confusion over the hiring of a Chief Executive Officer for Ruga. Mr. Lang responded that it was due to a miscommunication which probably occurred during the transition period between the resignation of his predecessor at CPRIT and his employment, a period of several months during which this award was being considered.

MOTION:

Presiding Officer Geren entertained a motion to authorize the Chief Executive Officer and staff to execute a contract with Ruga Corporation consistent with the Oversight Committee discussion regarding the company's activities to address the contract contingencies.

Motion was made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

Mr. Lang then presented an overview on two subjects to provide a common context for future discussions on target funding. He presented basic information on the cancer research and development landscape and the cancer venture capital investment landscape in Texas. He next presented a high level analysis of the CPRIT portfolio.

An Oversight Committee member asked for more information on the low-risk, high-risk ventures. Mr. Lang stated that the pharmaceutical companies have been highly studied. Many compounds are screened to identify those that are seemingly good drug candidates and about 4-5% of drug candidates that start the process actually get approved by the Food and Drug Administration (FDA). He explained that it is a multi-step process and there's attrition at various stages of the process. The preponderance of the failures happen in the first part of the process, before a full investment has been made. Because of the biological complexity involved, the attrition rate in pharmaceutical development is higher than in many other industries.

An Oversight Committee member asked where CPRIT investments fall on the spectrum of drug discovery to FDA approval, i.e., low, middle, high risk. Mr. Lang responded that CPRIT investments are mostly in the middle. Most drug FDA approvals are in the large pharmaceutical companies. Most of CPRIT investments are in the pre-clinical stage and can be expected to be sold to a large pharmaceutical company for final development.

An Oversight Committee member asked for information that categorizes companies by stage of development to be considered in the workshop on funding guidance. Mr. Lang said he has that information developed and will share it with the Oversight Committee prior to the workshop.

Another Oversight Committee member asked if within the US cancer research and development landscape devices and diagnostics are taking off and if CPRIT focuses too much on those instead of other promising areas that are coming up. Mr. Lang noted that in cancer there has been a revolution in diagnostics in the last 10 years. Molecular diagnostics are advancing cancer treatment significantly. The Oversight Committee member asked if the infrastructure that is needed to develop diagnostics and devices differs from the infrastructure needed for drug development. Mr. Lang responded that some of the infrastructure is the same, but much is different because the technologies are substantially different. He stated medical devices have been responsible for a significant impact in cardiovascular disease, but much less so in cancer due to the nature of the disease that has historically not lent itself to device therapies.

There were no further questions for Mr. Lang.

9. University Advisory Committee – Annual Report (Tab 9) ***(Agenda Item 12 taken out of order)***

Presiding Officer Geren introduced Dr. Mary Ann Ottinger, Vice-Chair of the University Advisory Committee (UAC) and Associate Vice-Chancellor for Research at the University of Houston, to present the UAC's annual report to the Oversight Committee.

Dr. Ottinger noted that the UAC annual report is in the meeting materials.

There were no questions for Dr. Ottinger.

10. Advisory Committee on Childhood Cancer – Annual Report (Tab 8) ***(Agenda Item 11 taken out of order)***

Presiding Officer Geren introduced Dr. Susan Blaney, Chair of the Advisory Committee on Childhood Cancer (ACCC) and Deputy Director of the Texas Children's Cancer Hematology Center and Executive Vice-Chair of the Department of Pediatric Oncology at Baylor College of Medicine. Dr. Blaney presented the ACCC annual report to the Oversight Committee. The report is also in the meeting materials.

Dr. Blaney also noted that the ACCC membership subcommittee discussed the instance in which an institution is a member, should it have more than one member, and if so, who? The committee decided that current members should maintain membership, but that input should be increased from across the pediatric oncology community in underserved areas of Texas. Therefore, ACCC proposes that non-member institutions nominate a non-voting member to serve on the advisory committee. Criteria would then be developed for non-voting members to ultimately become members. The subcommittee would also like to include ad hoc members as appropriate, increase the term of membership to three years with a limit of two terms, initiate membership rotation over the next year for continuity, and

modify the by-laws as appropriate.

An Oversight Committee member asked if the $10 million dollars in peer review funding to CPRIT-funded investigators was for the last year or the life of CPRIT. Dr. Blaney responded it was for the last year.

An Oversight Committee member asked if all members of the ACCC are from academic institutions. Dr. Blaney responded that currently, except for advocates, there is only one practicing pediatric oncologist on the committee with the remainder from academic institutions, which is why they recommend expanding the membership.

An Oversight Committee member asked if there are certain diseases that should be prioritized or de-prioritized by CPRIT—possibly that funding for diseases with very high cure rates should be decreased and funding for some incurable cancers be increased. Dr. Blaney responded that the answer is multifaceted. While many childhood cancers are now 80% curable, the non-targeted cures come with significant long-term side effects that lead to higher morbidity in adulthood. That means much research still needs to be dedicated to minimizing the toxicity of current therapies.

There were no further questions for Dr. Blaney. Presiding Officer Geren stated that the process for considering the recommendations coming from the advisory committees was unclear and stated it would be helpful to the Oversight Committee if staff put together a response to each of their recommendations. Dr. Kripke responded that, in the past, the advisory committees' comments were discussed in the Research Subcommittee of the Oversight Committee. Staff would then discuss point by point with the advisory committee to let them know which recommendations could be implemented and how, or why CPRIT could not implement a recommendation, so that there is continual dialogue. Going forward, Presiding Officer Geren stated he would like to have a summarization of the recommendations and CPRIT responses presented to the full Oversight Committee.

11. Scientific Research and Prevention Program Committee Appointments (TAB 6)
(Agenda Item 9 taken out of order)

Mr. Roberts presented the nomination of Dr. Karen Patricia Williams to the Scientific Research and Prevention Program Committee. Mr. Roberts also stated that Dr. Neil Spector and Dr. Robert Sarisky have been appointed to the Product Development Review Council but do not require Oversight Committee action because they are current members of the Scientific Research and Prevention Program Committee.

Presiding Officer Geren noted that the Nominations Subcommittee had recommended approval of Dr. Williams' proposed nomination.

MOTION:

Presiding Officer Geren called for a motion to approve appointment of Dr. Karen Patricia Williams to the Scientific Research and Prevention Program Committee.

Motion was made by Dr. Rosenfeld and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

12. Health & Safety Code § 102.1062 Waiver (TAB 7) ***(Agenda Item 10 taken out of order)***

Mr. Roberts presented the proposed conflict of interest waiver for FY 2016 for Program Integration Committee member Dr. John Hellerstedt, Commissioner of the Department of State Health Services.

MOTION:

Presiding Officer Geren called for a motion to approve the proposed conflict of interest waiver for Dr. Hellerstedt.

Motion was made by Dr. Rosenfeld and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

13. Chief Operating Officer Report (Tab 10)

Ms. Heidi McConnell, Chief Operating Officer, presented a report on CPRIT's fiscal year 2016 1st quarter financial overview, fiscal year 2016 1st quarter performance measures, and debt issuance history. She highlighted that, in terms of revenue, CPRIT collected $171,000 in conference fee registrations in November which was added to about $35,000 collected previously. CPRIT is still receiving conference registration payments. She also highlighted the debt issuance history. At the beginning of fiscal year 2015, CPRIT requested that the Texas Public Finance Authority issue $55.4 million in commercial paper notes on CPRIT's behalf to provide funds for CPRIT's fiscal year 2016 operating costs and grant award payments. The amount issued on CPRIT's behalf since the prior year totals $300 million in General Obligation Commercial Paper Notes, which includes $69.8 million for anticipated grant award expenses.

There were no questions for Ms. McConnell.

14. Internal Auditor Services Contract (Tab 11)

Ms. McConnell presented the staff recommendation to contract with Weaver and Tidwell for CPRIT's internal audit service contract for fiscal year 2016 in the amount of $232,500, including three one-year renewal options through the end of fiscal year 2019.

There were no questions for Ms. McConnell.

MOTION:

Presiding Officer Geren called for a motion to approve Weaver and Tidwell to perform internal audit services for fiscal year 2016.

Motion made by Mr. Holmes and seconded by Mr. Angelou.

MOTION CARRIED UNANIMOUSLY

15. Chief Compliance Officer Report (TAB 12)

Mr. Vince Burgess, Chief Compliance Officer, reported on the activities of the Compliance program. He noted that CPRIT has made an effort to increase internal communications and work with grantees to ensure that grantee reports are filed on time. Though a certain percentage of the approximately 500 reports due each month is expected to be missing or delinquent, statistics show a continued downward trend in terms of delinquent reports. The 13 delinquent reports on January 29, 2016, included 2 that were single audit determinations forms, 2 that were progress reports, 2 matching forms, and 7 financial status reports (FSRs). Mr. Burgess reported that 6 or 7 of the delinquencies were the result of a new grant being executed, which results in the system immediately showing subsequent reports due.

Mr. Burgess stated that at the November 19, 2016, Oversight Committee meeting staff was asked to perform an analysis of the reporting required by grantees. A report was presented to the Board Governance Subcommittee and prepared for the Audit Subcommittee. He stated that the report was located in the meeting materials along with a matrix of all required reports with associated information on who files, due dates, and applicable Texas Administrative Code and/or the Uniform Grant Managements Standards reference. Mr. Burgess said that the most common feedback from grantees concerns the amount of documentation required on the FSRs. Much of this need comes from State Auditor recommendations, internal audit recommendations, and financial audit findings indicating CPRIT had not required sufficient documentation. Therefore, CPRIT requires documentation for any expenses of $750 and over in some budget categories. For other budget categories, CPRIT requires full documentation.

An Oversight Committee member asked if staff requests clarification or questions regarding why the state asks for more documentation. Mr. Roberts responded findings are mostly derived from the January 2013 State Auditor's Office audit where 52 recommendations were made. Ten were directed to the Legislature. At the time, Mr. Roberts directed staff to accept all of the other recommendations unless they prohibited CPRIT from doing its job effectively. Additionally, Ms. Doyle stated that most of the 52 recommendations were incorporated by the Legislature into the CPRIT statutes.

An Oversight Committee member asked if the multiple reports due at the fiscal year end could be combined into one. Ms. Doyle responded that some of the year end reports cover different information from the annual reports. She stated that at one time all the different information was submitted as part of the annual progress report. Using this approach was difficult when disseminating the information to the various individuals that reviewed differing parts of the report. It was also difficult to remedy the problems arising from some parts of the report not being fully completed before submission. It has been determined it is no more difficult for the grantees to submit the information in separate reports, though it does

make their reporting requirements appear greater.

16. Proposed Amendments to 25 T.A.C. Chapters 702 and 703 and Authorization to Publish in *Texas Register* (Tab 13)

Ms. Kristen Doyle presented the proposed rule changes for 25 T.A.C. Chapters 702 and 703, which affect professional conflicts of interest, limitation on the use of grantee funds, and financial status report reimbursement reviews. Mr. Holmes, Chair of the Board of Governance Subcommittee, noted that the subcommittee recommended the Oversight Committee approve publication of the changes in the *Texas Register*.

MOTION:

Presiding Officer Geren called for a motion to approve the proposed rule changes for publications in the *Texas Register* for public comment.

Motion made by Mr. Montgomery and seconded by Dr. Rosenfeld.

MOTION CARRIED UNANIMOUSLY

17. Final Order Approving Amendments to 25 T.A.C. Chapter 703 (Tab 14)

Ms. Doyle presented for final approval by the Oversight Committee the amendments to 25 T.A.C. Chapter 703, which affect grant applications, matching funds, the prevention cap, no cost extension approval, tobacco-free policy waivers, grantee report due dates and the report approval process. These rule changes were preliminarily approved at the November 2015 Oversight Committee meeting. They were published in the *Texas Register* and public comments from two institutions were received and addressed.

MOTION:

Presiding Officer Geren called for a motion to approve the final order adopting CPRIT's rule changes and to direct staff to file the order with the Secretary of State.

Motion made by Mr. Montgomery and seconded by Mr. Holmes.

MOTION CARRIED UNANIMOUSLY

18. Subcommittee Business *(Agenda Item 19 taken out of order)*

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item regarding subcommittee business.

19. Compliance Investigation Pursuant to Health & Safety Code § 102.2631 *(Agenda Item 22)*

Presiding Officer Geren noted for the record that there was nothing to discuss under this standing item.

20. Future Meeting Dates and Agenda Items *(Agenda Item 24 taken out of order)*

The next regular Oversight Committee meeting will be May 18, 2016, at 10:00 a.m.

Special Presentation Honoring Dr. Margaret Kripke

Presiding Officer Geren recognized Dr. Margaret Kripke's retirement from CPRIT effective March 16, 2016. Mr. Roberts presented Dr. Kripke with a certificate from the Governor of Texas in appreciation of her service to Texas. Presiding Officer Geren proposed a resolution honoring Dr. Kripke for her service as Chief Scientific Officer for CPRIT.

MOTION:

Presiding Officer Geren called for a motion to approve the proposed resolution honoring Dr. Kripke for her service as Chief Scientific Officer for CPRIT.

Motion made by Dr. Rice and seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

21. **Proposed Settlement – Peloton Therapeutics *(Agenda Item 21 taken out of order)***
22. **Public Information Act and Open Meeting Act Update Training (Tab 15) (*Agenda Item 18 taken out of order*)**
23. **Personnel – Chief Executive Officer Annual Evaluation *(Agenda Item 20 taken out of order)***
24. **Consultation with General Counsel *(Agenda Item 23 taken out of order)***

Presiding Officer Geren announced the Oversight Committee would go into closed session to take up out of order and together: Item 18, Public Information Act and Open Meeting Act Update Training; Item 20, Personnel – Chief Executive Officer Annual Evaluation; Item 21, Proposed Settlement – Peloton Therapeutics; and Item 23, Consultation with General Counsel; and will seek legal advice in closed session.

Pursuant to Texas Open Meetings Act Section 551.071 and 551.074, the Oversight Committee went into closed session to consult with legal counsel and discuss personnel matters. The following CPRIT staff were asked to join the Oversight Committee in the closed session: Kristen Doyle, Wayne Roberts, and Cameron Eckel.

Presiding Officer Geren convened in closed session at 12:33 p.m.

Presiding Officer Geren reconvened the open meeting at 2:03 p.m.

MOTION:

Presiding Officer Geren called for a motion to authorize the Chief Executive Officer to negotiate and execute a settlement with Peloton Therapeutics consistent with the guidance and terms discussed during closed session.

Motion made by Mr. Holmes and seconded by Mr. Margo.

MOTION CARRIED UNANIMOUSLY

25. Adjourn

MOTION:

There being no further business, Presiding Officer Geren made a motion to adjourn.

Motion was seconded by Mr. Montgomery.

MOTION CARRIED UNANIMOUSLY

Meeting adjourned at 2:05 p.m.

_____ _____

Signature Date

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	AGENDA ITEM 5, CHIEF EXECUTIVE OFFICER REPORT
DATE:	MAY 12, 2016

As of this writing the Chief Executive Officer Report for the May 18, 2016, Oversight Committee will consist of the following items:

- Personnel update, including introduction of new staff
- Action Items from February 17, 2016, Oversight Committee Meeting (see following memorandum)
- 2016 Customer Service Survey
- Report on "FY 2016 Grant Award Funds Available" (see following attachment)

In addition, for your reference, copies of the CPRIT Activities Updates for March and April previously provided to you are included at the end of this tab. These are the reports provided to you in months in which the Oversight Committee does not meet.

Other topics may be added as warranted.

*****

CPRIT has awarded **998** grants totaling **$1.496 billion**

- 158 prevention awards totaling $155.4 million
- 840 academic research and product development research awards totaling $1.341 billion

Of the $1.341 billion in academic research and product development awards,

- 30.7% of the funding ($411.6 million) supports clinical research projects
- 25.6% of the funding ($342.6 million) supports translational research projects
- 24.9% of funding ($334.2 million) supports recruitment awards
- 15.5% of the funding ($208.2 million) supports discovery stage research projects
- 3.3% of funding ($44.4 million) supports training programs.

CPRIT has 3 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 6 Academic Research

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	ACTION ITEMS FROM FEBRUARY 17, 2016 OC MEETING
DATE:	MAY 12, 2016

Summary:

This report updates the Oversight Committee on implementation of action items from the February 17, 2016, meeting.

Discussion:

The Oversight Committee requested CPRIT staff address several issues following the February 17, 2016, Oversight Committee meeting. This memo provides a summary for each item, its status, next steps, and assigned CPRIT staff members.

Prevention Awards 10% Statutory Cap Issue (Wayne Roberts, Heidi McConnell, Becky Garcia, Kristen Doyle, Jim Willson)

The prior years' over-award of $2,776,365 was resolved at the February 17 Oversight Committee meeting by reducing FY 2016 Prevention Program awards by $924,530. FY 2017 Prevention Program awards will be reduced by the remainder, expected to be $1,851,835. These reductions align CPRIT's Prevention awards with the statutory cap.

- Status: The "FY 2016 Grant Award Funds Available" worksheet provided to the Oversight Committee for the May 18, 2016, meeting is updated to reflect the Oversight Committee's decision. The Prevention Program is scheduled to present award recommendations for Oversight Committee consideration at the August 17 meeting. Proposed award amounts will be adjusted, if necessary, to be less than the revised cap.

- Next steps: Academic Research is considering establishing a time limit on acceptance of recruitment awards. The declination of recruitment awards after the fiscal year closes is one of the main reasons that the Prevention Program funding has exceeded the 10% statutory limit.

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Research Programs Funding Targets for FY 2016 (Wayne Roberts, Jim Willson, Mike Lang, Becky Garcia)

The Oversight Committee moved the resolution of this issue to the May 18 Oversight Committee meeting and a special work session on May 19. The issue was divided into two parts: 1) possible funding shortfall in FY 2016, and 2) long-term budget target setting

- Status: The Program Integration Committee discussed options to address the **FY 2016 shortfall**. The PIC proposes addressing the shortfall through a combination of efforts, including: deferring some academic research decisions until the August Oversight Committee meeting; reducing the amounts of other awards; and taking up recruitment applications submitted this summer at a special Oversight Committee meeting held once the new fiscal year starts in September. In addition, Mike Lang discussed budget needs with two potential Product Development awardees pursuant to a waiver granted by me. Mr. Lang will recommend that the Oversight Committee reduce the requested awards by $2.9 million, which frees up some FY 2016 award funds.

  Ideas to prioritize applications in the event of any future funding shortfalls and **long term budget target setting** will be discussed at the May 19 Work Session. We recommend that the budget planning discussion be combined with the Program Priorities discussion. The Program Priorities are due for revision or re-adoption in November 2016. Additional detail on these ideas as well as the funding history for each program will be provided in materials for the May 19 Work Session.

- Next steps: Consideration and discussion of program budget targeting and the Program Priorities at the May 19 Work Session.

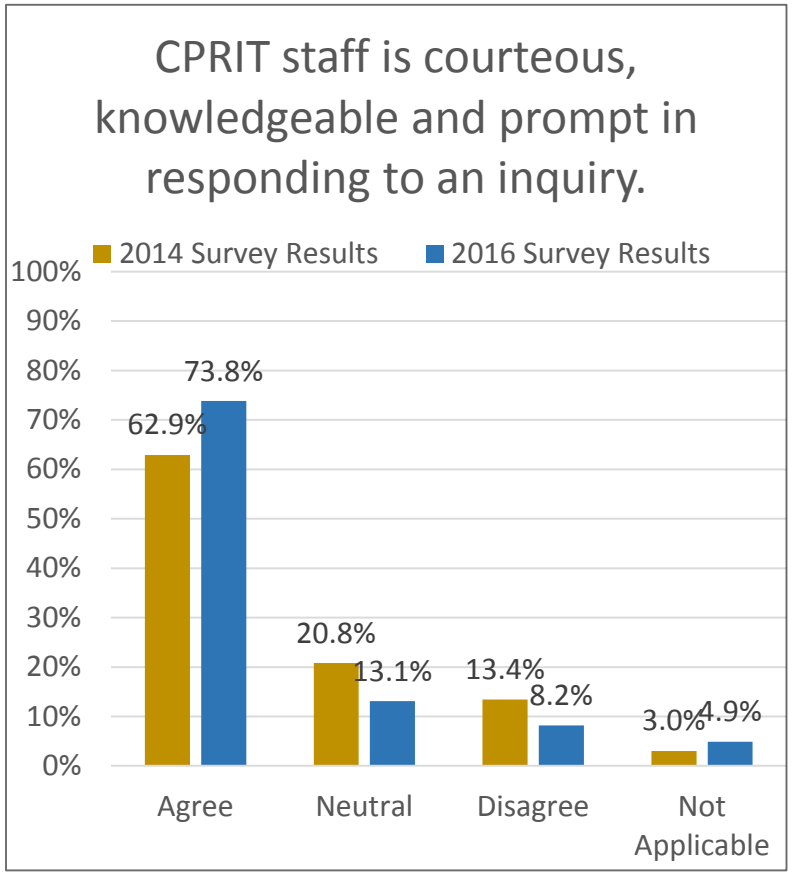
Program Presentation Material (Kristen Doyle, Program Staff)

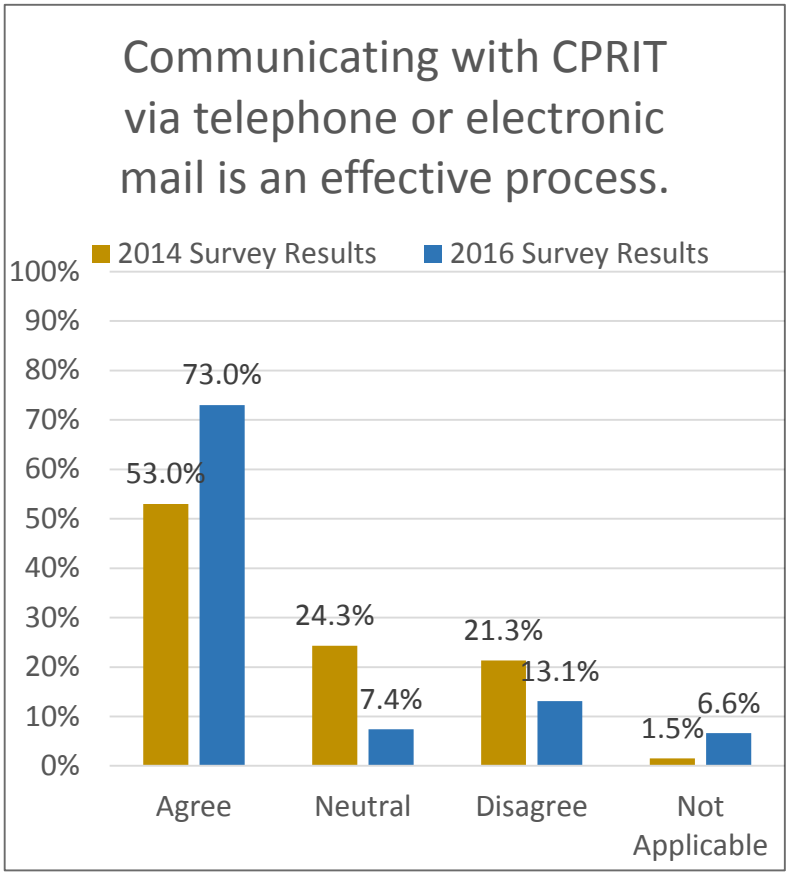
The Oversight Committee requested that CPRIT's three programs clearly show how proposed awards meet the Oversight Committee's Program Priorities. Program Officers should provide this information when the Oversight Committee considers the grant recommendations. Generally, the Oversight Committee requested that the three programs follow a uniform format when presenting certain information about award recommendations and limit the use of acronyms.

- Status: Both Academic and Product Development Research have funding recommendations for the May 18, 2016, Oversight Committee meeting. The programs created a cover page for the funding recommendations that specify the Oversight Committee's priorities addressed by the proposed grants. Dr. Willson and Mr. Lang both followed a standard format for their memos explaining the award recommendations.

- Next Steps: CPRIT staff will seek feedback from the Oversight Committee regarding presentation of award materials.

CPRIT Customer Service Survey Results: 2016 Compared to 2014





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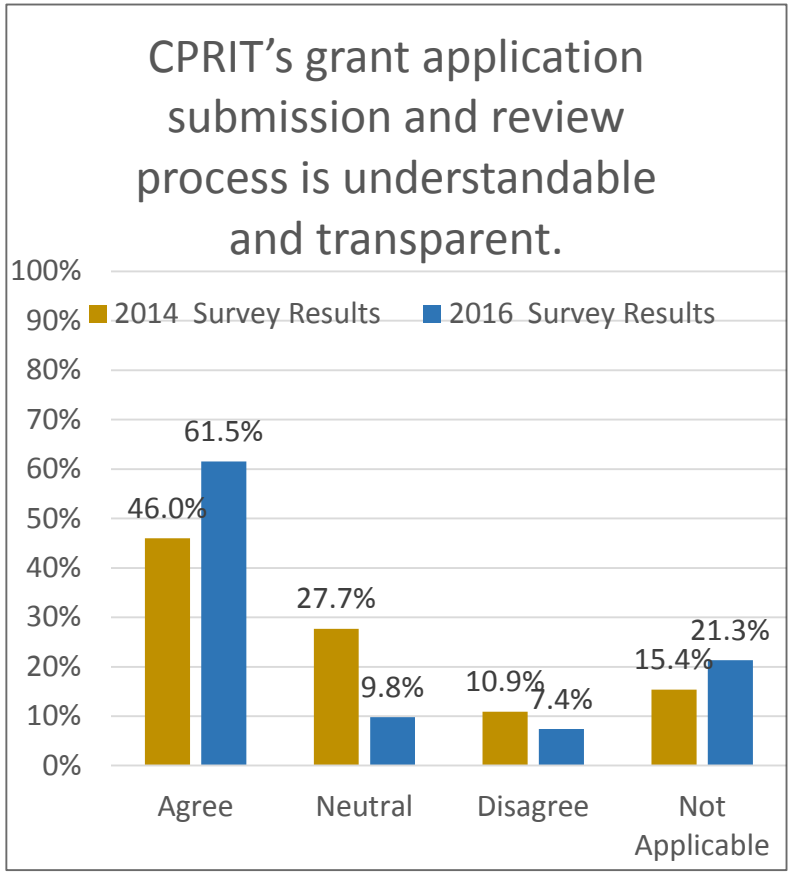
CPRIT Customer Service Survey Results: 2016 Compared to 2014



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FY 2016 GRANT AWARD FUNDS AVAILABLE

General Obligation Bond Proceeds

	Prevention	Academic / PD Research	Prevention Percentage Based on Available Award Appropriations	Operating Budget	Total Appropriations
Available Appropriated Funds	$ 28,325,035	$ 254,925,317		$ 16,749,648	$ 300,000,000
Unexpended Bond Proceeds Carry Forward		$ -			$ -
Unexpended Balance Carry Forward		$ -			
Approved Adjustment to Operating Costs		$ (621,952)		$ 621,952	
Appropriations Transfer to DSHS		$ (2,969,554)		$ 2,969,554	
Adjusted Appropriations	$ 28,325,035	$ 251,333,811		$ 20,341,154	$ 300,000,000
Total Available for All Grants			$ 279,658,846		
Calculated 10% for Prevention Grants of Total Available Grant Funding			$ 27,965,885		
Adjustment for 10% Prevention Grants Limit	(359,150)	$ 359,150			
Adjustment to Address Avg Prev Historical Limi	(924,530)	$ 924,530			
Revised Adjusted Appropriations	$ 27,041,355	$ 252,617,491		$ 20,341,154	$ 300,000,000
Total Available for Grant Awards (Total GO Bond Proceeds Less Operating Budget)	$ 27,041,355	$ 252,617,491			$ 279,658,846
Announced Grants					
9/10/15 Rsch Recruitment Awards		$ 17,700,000			
11/19/15 Rsch Recruitment Awards		$ 16,000,000			
11/19/15 Rsch Awards-IIRA		$ 34,744,442			
11/19/15 Rsch Training		$ 14,966,408			
11/19/15 PD Awards		$ 20,000,000			
11/19/15 Prevention Awards	$ 13,247,742				
2/17/16 Rsch Recruitment Awards (w/withdrawals)		$ 26,000,000			
Announced Grant Award Subtotal	$ 13,247,742	$ 129,410,850	$ -		$ 142,658,592
Grant Award Adjustments					
Declined Recruit Award (UTSW) 2/2016 Slate		$ (2,000,000)			$ (2,000,000)
Revised Grant Award Subtotal	$ 13,247,742	$ 127,410,850			$ 140,658,592
Adjusted Available Funds Post Feb. 2016	$ 13,793,613	$ 125,206,641			$ 139,000,254
Pending Grants-PIC Recommendations					
PD Research Grant Recs-Adjusted Budgets		$ 33,913,939			
Academic Research Grant Recs		$ 34,523,901			
Scientific Recruits (16.8 & 16.9)		$ 10,823,067			
Pending Award Subtotal	$ -	$ 79,260,907			$ 79,260,907
Total Potential Grant Funding Committed	$ 13,247,742	$ 208,671,757			$ 221,919,499
Available Funds as of May 11, 2016	$ 13,793,613	$ 45,945,734			$ 59,739,347
PIC Deferred Academic Research Grants		$ 44,602,336			

Operating Budget Detail	
Indirect Administration	$ 3,003,133
Grant Review & Award Operations	$ 14,368,467
Subtotal, CPRIT Operating Costs	$ 17,371,600
Cancer Registry Operating Cost Transfer	$ 2,969,554
Total, Operating Costs	20,341,154

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
ACCOUNTABILITY														
Announced Grant Awards	5		77			6							88	
New Grant Contracts Signed	8	0	1	4	25	31	10	5					84	
New Grant Contracts In			43			24							67	
Grant Reimbursements Processed	31	7	266	208	529	245	294	129					1,709	
Grant Reimbursements Processed	$ 2,897,094	$ 23,414,469	$ 19,906,130	$ 21,102,375	$ 41,408,221	$ 19,447,324	$ 23,751,614	$ 12,000,762					$ 163,927,989	
Revenue Sharing Payments	$ -	$ 10,117	$ 4,959	$ -	$ 21,122	$ -	$ -	$ 9,358					$ 45,556	$ 2,259,073
Total Value of Grants Contracted	$ 49,662,860	$ -	$2,000,000	$ 9,202,957	$ 42,908,491	$ 40,857,638	$ 14,512,920	$ 6,058,940					$ 165,203,806	
Grants Awarded (#)/ Applications Rec'd (#)	12%	11%	13%	13%	13%	13%	12%	12%						
Debt Issued ($)/Funding Awarded	62%	62%	58%	58%	62%	61%	61%	61%						
Grantee Compliance Trainings/Monitoring Visits	3	2	2	0	3	0	3	0					13	
Awards with Delinquent Reimbursement Submission (FSR)			5			3								
Awards with Delinquent Matching Funds Verification			10			3								
Awards with Delinquent Progress Report Submission			4			3								
IA Agency Operational Recommendations Implemented	0	6	6	6	6	6	6	6						
IA Agency Operational Recommendations In Progress	13	7	7	7	7	7	7	7						
Open RFAs	17	14	9	9	11	11	15	9						
Prevention Applications Received	0	0	0	0	0	0	44	0					44	549
Product Development Applications Received	25	0	0	0	0	32	0	0					57	309
Research Applications Received	4	212	2	6	5	5	9	13					256	4,039
Help Desk Calls/Emails	193	289	231	159	143	323	191	300					1,829	
MISSION														
RESEARCH PROGRAM														
Number of Research Grants Awarded (Annual)			55			6							61	
Recruited Scientists Announced														137
Recruited Scientists Accepted														108
Recruited Scientists Contracted														95
Published Articles on CPRIT-Funded Projects (#)														
Jobs Created & Maintained (#)														
Trainees in CPRIT-Funded Training Programs (#)														
Open Clinical Trials (#)														53
Number of Patents Resulting from Research														
Number of Patent Applications														

CPRIT MANAGEMENT DASHBOARD
FISCAL YEAR 2016

	SEPT	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	CUMULATIVE (ANNUAL)	CUMULATIVE (TO DATE)
Number of Investigational New Drugs														
PRODUCT DEVELOPMENT PROGRAM														
Number of Product Development Grant Awarded (Annual)			1			0							1	
Life Science Companies Recruited (in TX)														7
Published Articles on CPRIT-Funded Projects														
Number of Jobs Created & Maintained														
Open Clinical Trials (#)														7
Number of Patents Resulting from Research														
Number of Patent Applications														
Number of Investigational New Drugs														
PREVENTION PROGRAM														
Number of Prevention Grant Awarded (Annual)			12			0							12	
People Served by CPRIT-Funded Prevention and Control Activities			120,112			130,335							250,447	
People Served through CPRIT-Funded Education and Training			58,126			55,377							113,503	
People Served through CPRIT-Funded Clinical Services			61,986			74,958							136,944	
TRANSPARENCY														
Total Website Hits (Sessions)	8,560	7,901	8,581	4,617	5,993	7,458	7,031	7,001					57,142	
Total Unique Visitors to Website (Users)	5,778	5,472	5,679	3,376	4,435	5,251	4,916	4,789					39,696	

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	CPRIT ACTIVITIES UPDATE – APRIL 2016
DATE:	MAY 2, 2016

Topics in the memo include: recent milestones in our fight against cancer; CPRIT staffing; legislative briefings and staff presentations; executive management training; Compliance, Program, and Operations updates; and preparation for the May 18 Oversight Committee meeting.

Please note: we have three important CPRIT events May 17-19. These are:

- May 17 - Halfway Point Celebration and Media Event, 1:00 p.m., Capitol Extension Auditorium
- May 18 - Oversight Committee Meeting, 10:00 a.m., Extension E1.012
- May 19 - Oversight Committee Work Session on Program Budget Targeting, 8:30 a.m. Robert E. Johnson Building Conference Center

Preparation for the May Oversight Committee Meeting

The Oversight Committee is scheduled to meet May 18 at 10:00 a.m. in the Capitol Extension. The final agenda for the Oversight Committee meeting will be posted by May 10; a tentative agenda is attached. The Academic Research and Product Development Research programs will have award recommendations to be considered by the Oversight Committee. Other major agenda items include the presentation of four internal audit reports, the FY 2016-2018 internal audit plan, several proposed rule and bylaw changes.

You will receive an email from CPRIT by May 6 with a link and password to access the PIC's recommendations via the grant award portal. The portal has supporting documentation regarding each project proposed for an award, including the application, CEO affidavit, summary statement, and grant pedigree. A summary of the award slate will also be available through the portal. There will be a large number of recommended awards, please allow time to complete the individual conflict of interest checks and review the supporting material.

Oversight Committee members should receive an electronic copy of the agenda packet by COB May 11. Hard copies of the agenda packet will be available at the May 18 meeting.

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Expected September Oversight Committee Meeting

A special Oversight Committee meeting is needed in September to review recruitment award recommendations. The best window for this meeting to be held is the week of September 12. Mary Gerdes will conduct a Doodle poll by email to select a date that week.

Recent Milestones in the Fight Against Cancer (Academic Research, Product Development Research, Prevention)

CPRIT-funded Prevention programs are now in all 254 counties.

CPRIT Product Development Research grantee Asuragen announced the upcoming launch of a new diagnostic product for lung cancer. Their new product was developed in conjunction with MD Anderson Cancer Center and provides improved turnaround time and lower costs.

Pulmotect completed a second clinical trial to characterize the safety of its lead drug candidate, PUL-042. Additionally, the CPRIT-funded company closed on an initial $1.75 million Series A investment and was awarded another $1 million grant from the National Heart, Lung, and Blood Institute of the National Institutes of Health.

Another Product Development Research grantee, Mirna, reported new pre-clinical data at the American Association of Cancer Research conference, showing that two of the company's key compounds work synergistically with current cancer therapies.

Personnel Changes and Job Openings

CPRIT has 32 authorized full-time equivalent (FTE) positions, of which 29 are filled as of April 30, 2016.

- The vacant Grant Compliance Specialist position closed and interviews are in progress.
- The vacant Grant Accountant position is posted until May 6.
- The vacant Program Manager for Academic Research position closed on April 29. Applications are currently being screened.

Executive Management Training

In consultation with Oversight Committee members Ned Holmes and Dee Margo, Kristen Doyle, Heidi McConnell and I investigated options for senior staff management and team development training. Four executive training contractors were identified that may be able to provide the desired training. Three options were not based in Texas. Any training agreement must comply with strict state consulting and contracting requirements. As a result, it appears that the Governor's Executive Development Program operated by the LBJ School of Public Affairs at The University of Texas at Austin is our best option. We hope to schedule the training this summer.

CEO Cancer Gold Standard

CPRIT was notified on April 29 that the agency was re-accredited as a CEO Cancer Gold Standard employer for 2016. This award, presented annually by the CEO Roundtable on Cancer, is given for meeting standards for workplace wellness programs and dedication to employee health and well-being.

Legislative Briefings and CPRIT Presentations

- Kristen Doyle, Becky Garcia and I met with Representative Four Price on April 5 to report on CPRIT's activities.

- Mike Lang attended the RESI (Redefining Early State Investments) conference in Houston on April 11. He participated as a panelist on the "Early Stage Therapeutics Investors" panel and met with approximately 25 prospective applicants.

- I met with the director of the Governor's Office Budget Division on April 18 to discuss state strategic planning and budget issues and to provide an update on CPRIT activities.

- Jim Willson, Jeff Hillery and I met with Annette Leslie, Co-Chair of the Carson Leslie Foundation and a member of CPRIT's Advisory Committee on Childhood Cancers about possible CPRIT participation in the Congressional Caucus on Childhood Cancer 's annual conference and related events planned for September 22 and 23, 2016, in Washington, D.C.

- Vince Burgess, Ramona Magid, Cameron Eckel and Oralia Huggins presented "Being a CPRIT Grantee: What You Need to Know" at the National Council of University Research Administrators (NCURA) Region V meeting in Dallas on April 25. The training covered grantee reporting requirements, an overview of the compliance program, a review of the most frequent compliance monitoring findings, and recent administrative rule changes.

- Michael Lang, Kristen Doyle and I will attend the BIO International Convention June 6 – 9 in San Francisco. BIO attracts over 15,000 biotechnology and pharmaceutical leaders interested in life science partnerships. CPRIT will be part of a coalition representing Texas.

- CPRIT's Compliance Program staff will conduct a grantee training webinar on June 15 for current grantees. This will be the second webinar planned for grantees in support of the new annual compliance training requirement that the Authorized Signing Official (ASO) and at least one other employee from each grantee organization must attend an annual compliance training by November 1 of each year.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

As of the most recent CGMS report (April 22, 2016), 10 required grantee reports from 7 entities have not been filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed and approved by CPRIT. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted for approval. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to promptly resolve filing issues.

FSR Reviews

CPRIT's Grant Compliance Specialists performed 92 second-level reviews of grantee Financial Status Reports (FSRs) during the month of April. Only three FSRs required resubmission due to insufficient documentation submitted by the grantee. CPRIT's grant accounting staff completes the initial review of the FSRs and supporting documentation before routing them to the compliance specialists for final review and disposition.

Desk Reviews

Eighteen desk reviews were performed during the month of April, bringing the FY 2016 year-to-date total to 195 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year. During the month of April, one grantee submitted the appropriate documentation to fully remediate audit findings. There are currently no grantees with outstanding audit findings. Grant compliance specialists are working with three grantees regarding delinquent audit reports. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective

action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Academic Research Program Update

The Scientific Review Council (SRC) reviewed 200 research grants and 19 recruitment nominations this quarter and has recommended awards that total $92,596,133. The SRC's recommendations will be considered by the PIC on May 3.

Academic Research Review Cycle 16.2 Scientific Review Council Grant Review

Thirty-four of 200 submitted applications reviewed in March were recommended by the SRC for a total of $81,773,066. These include six Core Facility Support Awards (CFSA), seven Multi-Investigator Research Awards (MIRA), and 21 High Impact/High Risk Awards (HIHR).

Academic Research Review Cycles 16.7-16.9 Recruitment Review

During the third quarter of FY 2016, the SRC reviewed 14 Recruitment Awards for First Time Tenure Track Faculty and recommended six for a total of $10,823,067. Three Established Investigator and three Rising Stars applications were reviewed but none were recommended. Based upon historic data, we expect that the SRC will recommend an additional $20-30 million in recruitment awards during the final quarter of FY 2016. In May, the SRC will review 13 recruitment applications requesting a total of $44 million.

Because of budget limitations and the unknown impact of the recruitment award recommendations to made in the final quarter of FY 2016, it may not be feasible to fund all SRC recommended awards in FY 2016. We will recommend deferring funding decisions for several large MIRAs and CFSAs to the August 2016 Oversight Committee meeting and taking up funding decisions for new recruitment nominations submitted this summer at a special Oversight Committee meeting in September (FY 2017).

Academic Research Review Cycle 17.1 Request for Applications

Research RFAs for 17.1 were posted on February 19, 2016. Applications are accepted March 21 through May 19. The applications will be evaluated at peer review meetings in September, and grant recommendations will come to the November 2016 Oversight Committee meeting for approval. These RFAs include Research Training Awards, untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Childhood and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Individual Investigator Research Awards for Computational Biology (IIRACB), and Early Translational Research Awards (ETRA).

University Advisory Committee

The University Advisory Committee (UAC) met via teleconference on April 25, 2016. Mary Ann Ottinger Ph.D., Associate Vice Chancellor for Research, University of Houston System, has assumed the UAC chair and two new members have been appointed:

- Michelle C. Barton, Ph.D., from MD Anderson Cancer replaces Dr. Willson as the UT System representative
- Mike Blanda, Ph.D., replaces Dr. Bill Covington as the representative from the Texas State University System.

Dr. Willson and I participated in the conference call and provided updates as well as engaged in discussions with the Committee on plans for the future.

Dr. Willson discussed his vision for the CPRIT Research Program portfolio and led a discussion of the UAC recommendations made in their 2015 annual report to the Oversight Committee. The Committee identified support for clinical trials research and development of outcome metrics to evaluate the success of CPRIT programs. The UAC plans a retreat in June to discuss an action plan to address these and other issues that will frame the Committee agenda for the next year.

Advisory Committee on Childhood Cancer (ACCC)

The ACCC met via teleconference on April 26, 2016. Dr. Willson and I participated and provided updates on the impact of recent Core Facility Support and Investigator initiated RFAs that target Childhood Cancers. There were five Investigator Initiated Research Awards in Childhood Cancer awarded in FY 2016, and there was a robust response from the pediatric cancer community to the recent Core Facility Support RFA.

The conference call provided Dr. Willson the opportunity to share his vision for the CPRIT Research Program and to hear from the ACCC members their recommendations of mechanisms to further strengthen pediatric cancer research in Texas. ACCC members discussed several examples of the impact CPRIT has had on pediatric research and care. One notable example discussed was the PASSPORT for Care, a program supported by CPRIT's Prevention Program to provide survivors of pediatric cancer access to portable medical records and surveillance recommendations. This program is an example of a CPRIT supported collaboration that engages multiple institutions across Texas and developed best practices that are now being adopted outside Texas. The ACCC plans quarterly teleconference calls to advise CPRIT on opportunities to catalyze cooperative programs that leverage pediatric cancer expertise across Texas.

Product Development Research Program Update

Product Development Review Cycle 16.1 Applications Due Diligence Complete

In December, the Product Development Research peer review panels recommended five applicants for due diligence review. The business/regulatory due diligence and intellectual property reviews were completed and provided for Product Development Review Council (PDRC) consideration in March. The PDRC recommends that two of the five projects receive grant funding. The PIC will consider the recommendations on May 3 in preparation for the May 18 Oversight Committee meeting. The total amount requested is $36,833,000.

Product Development Review Cycle 16.2 Applicants Preparing for Peer Review

CPRIT posted requests for Texas Company and Company Relocation applications in December. Thirty-two applications were submitted by the February 25 deadline, making this among our largest submission pools. The screening teleconference was held April 7 & 8. Thirteen applicants were selected to present at the peer review panel meetings on May 10-12. Award recommendations from this cycle are expected to be considered by the Oversight Committee in September or November.

Award Contracts

We are finalizing contracts with two grantees: Ruga and Vermillion.

Product Development Review Process

We are collaborating with the PDRC to improve the review process. One effort is to improve the quality and applicability of due diligence review. Mike Lang met with CPRIT's third party review contractors to review and plan potential changes in report structure. Numerous improvement opportunities were identified with implementation underway.

In addition to improvements to the due diligence review process, Mr. Lang is revising RFAs to incorporate several potential policy changes including:

- Highlighting CPRIT interest in funding all sectors that impact cancer care (therapeutics, diagnostics, devices, etc.)
- Objective criteria defining Texas location
- Streamlining CPRIT's investment policy to focus on preclinical and Phase I and IIA stages of development
- Clarifying CPRIT's investment policy to avoid multiple awards to the same companies.

The Product Development Research program also launched a process to review business plans submitted in conjunction with Early Translational Research Awards (ETRA) grants, which are

part of the Academic Research portfolio. All 19 ETRA grantees submitted business plans and the review and feedback process is underway.

Product Development Strategy

Specific strategies to optimize CPRIT's impact are being explored:

- University Spinout Support - Supporting new company formation and launch is synergistic with our mission, and Texas academic institutions have expressed interest in collaborating. More in- depth discussions with institutions and further assessment is required to assess fully the viability of this idea.

- Equity Holdings- CPRIT holds equity in three firms and likely will have additional equity holdings in the future. A proposal on equity holding strategy is being developed for Oversight Committee consideration.

An initial presentation on these issues has discussed with most Oversight Committee members and some of the issues will be discussed at the May 19 Oversight Committee work session.

Prevention Program Update

FY 2016 Review Cycle 2 Prevention Applications – Under Review

Six Requests for Applications (RFAs) were released on September 24, 2015. Forty-four applications were received by March 3, more than doubling the number of applications received the previous cycle. Dr. Garcia and Ms. Magid visited several parts of the state over the past several months to encourage applications; some of these new applications are a direct result of those efforts. Assignments have been made to peer reviewers. The peer review panels will meet May 23-25 in Dallas. A webinar briefing for new and returning reviewers was conducted April 18.

FY 2017 Review Cycle 1 Request for Prevention Applications to be released in May

RFAs for Cycle 17.1 are being revised and updated for release in May. Applications will be due August 30 and any recommendations are expected to be presented for PIC and Oversight Committee consideration in February 2017.

Other activities

- Geographic coverage: In the quarterly reports due March 15, some grantees reported serving more counties than originally proposed. One grantee reported serving people from the two counties (Hamilton and Coryell) that had not previously been covered by direct services. While the program has always included web-based and other projects serving all counties in the state, this is the first time the Prevention program can claim, that at some point in the program's history, people in every county have had a direct service provided by a CPRIT grantee.

- A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor. The revised report will be tested with a few grantees prior to its release.

Communications Update

CPRIT Messages

- Communications staff are making plans for the event celebrating CPRIT's half-way point in awarding the $3 billion entrusted to it to fight cancer. CPRIT will host the event at the Capitol Extension Auditorium on May 17, 2016, at 1:00-3:30 pm. The three Chief Program Officers will report on the state of their programs including key metrics and signature discoveries to date. We will also showcase a select group of CPRIT grantees whose projects demonstrate significant progress towards our mission. Legislators, cancer advocates and the media have been invited to this event.

- CPRIT conducted a test of the "Significance Project" survey with a small sample of grantees. The survey was revised and sent out to a larger group of grantees. Responses are due May 5.

- 2017 Conference. Planning for the 2017 Conference has begun with the selection of meeting planning services. Swift Solutions, the vendor that assisted us with the 2015 conference, was awarded the contract. The next step is to release a Request for Proposals (RFP) for a hotel venue. The plan is to present the hotel contract to the Oversight Committee in August for consideration.

- Communications staff worked with IT and the procurement staff to issue the request for offer and to evaluate the applicants for the Website redesign services.

- Staff continues to prepare legislative briefing materials as needed.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

Operations and Finance (Contracts, RFPs, Audit)

Contracts

As reported above, CPRIT staff selected Swift Solutions Events located in Austin, Texas, to provide conference planning and coordination services for the 2017 CPRIT conference. CPRIT will award the $65,000 contract when all financial conflict of interest responses from Oversight

Committee members have been received. Because the contract is under $100,000, the Oversight Committee does not need to take any formal action at the May meeting.

Request for Offer

CPRIT issued a Request for Offer (RFO) to redesign CPRIT's website to website design vendors available through the Department of Information Resources cooperative contracts program on March 30, 2016. The RFO closed on April 20, 2016, and four vendors submitted proposals to CPRIT. CPRIT staff has reviewed and evaluated the proposals and is moving forward with interviews of selected vendors. We are finalizing pricing. If the contract exceeds $100,000, then it will be presented to the Oversight Committee in May for consideration.

State Agency Strategic Planning

On April 6, the Governor's Office and Legislative Budget Board (LBB) jointly issued instructions to state agencies for preparing and submitting their strategic plans for fiscal years 2017 through 2021. The submission of the strategic plan is the first step in the state budget process on agency budgets for the 2018-19 biennium which will be considered by the Texas Legislature when it convenes for the 85th Regular Session in January 2017. CPRIT's strategic plan is due by June 24, 2016.

Heidi McConnell is coordinating the agency's compilation of information for the plan. The process will be discussed with the Oversight Committee at the May meeting. The strategic plan includes the agency's budget structure and performance measures. The agency has submitted a request to change an existing performance measure, delete one existing performance measure, and add one new measure. These revisions require approval by the Governor's Office and LBB before they can be incorporated in the agency's strategic plan. Given the timing, a draft plan will not be provided by the May meeting but will be distributed to the Oversight Committee once all of the information has been compiled and before the required submission date.

Statewide Centralized Purchasing Study (SB 20)

Heidi McConnell and Don Brandy are completing responses to a Centralized Purchasing Study questionnaire for the Comptroller of Public Accounts (CPA). Senate Bill 20 from the 2015 legislative session mandated that the CPA conduct this study. CPRIT is one of 109 agencies that have been requested to complete the questionnaire.

2016 CPRIT Grant Policies and Procedures Guide

Over the past several months, CPRIT staff has reviewed agency policies and procedures addressing all aspects of the grant process - from submitting a grant application to closing out a grant project. As a result of this comprehensive months-long process, CPRIT legal staff has created a new *CPRIT Grant Policies & Procedures Guide* that CPRIT plans to release in May.

The guide brings together the various CPRIT requirements and policies affecting grant applicants and grantees (*e.g.* the Request for Applications, CPRIT's statute and administrative rules, the

state's Uniform Grant Management Standards, the grant contract, CPRIT's application receipt system and grant management system) in an easy-to-follow format. Its main purpose is to give advice and guidance to individuals outside our agency applying for or receiving CPRIT grants.

Despite its name, the *CPRIT Policies & Procedures Guide* is not the vehicle for CPRIT to *establish* policy. State law requires the agency to set policy through the administrative rulemaking process in order for the policy to be legally enforceable. Legal staff has identified some issues that would benefit from additional clarification in the grant RFA, award contract, or administrative rules. Kristen Doyle will bring the proposed rules to the Oversight Committee in August for preliminary consideration.

Upcoming Oversight Committee-related Meetings

The Oversight Committee will hold its next meeting on May 18, 2016, at 10:00 am in the Capitol Extension. Please note that the start time of the May meeting is different from the February meeting. The Oversight Committee voted to use the 10:00 start time as the standard going forward.

The dates and times for the upcoming May subcommittee meetings are listed below.

Board Governance –	May 5 at 10:00 am
Diversity –	May 6 at 10:30 am
Audit –	May 9 at 10:00 am
Prevention –	May 10 at 10:00 am
Scientific Research –	May 11 at 10:00 am
Product Development –	May 12 at 10:00 am
Nominations –	May 13 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date.

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CPRIT has awarded **998** grants totaling **$1.496 billion**

- 158 prevention awards totaling $155.4 million
- 840 academic research and product development research awards totaling $1.341 billion

Of the $1.341 billion in academic research and product development awards,

- 30.7% of the funding ($411.6 million) supports clinical research projects
- 25.6% of the funding ($342.6 million) supports translational research projects
- 24.9% of funding ($334.2 million) supports recruitment awards
- 15.5% of the funding ($208.2 million) supports discovery stage research projects
- 3.3% of funding ($44.4 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 6 Academic Research

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER

SUBJECT: CPRIT ACTIVITIES UPDATE – MARCH 2016

DATE: APRIL 4, 2016

Topics in the memo include: recent milestones in our fight against cancer; CPRIT staffing; legislative and related briefings; strategic planning; executive management training; Compliance, Program, and Operations updates; and staff presentations and meetings.

Please note: we have three important CPRIT events May 17-19. These are:

- May 17 - Halfway Point Celebration, 1:00 pm, Capitol Extension Auditorium
- May 18 - Oversight Committee Meeting, 10:00 am, Extension E1.012
- May 19 - Oversight Committee Work Session on Program Budget Targeting, Robert E. Johnson Building

Recent Milestones in the Fight Against Cancer (Academic Research, Product Development Research, Prevention)

Vermillion, Inc., a diagnostics company focused on gynecologic disease, announced receipt of 510(k) marketing clearance from the U.S. Food and Drug Administration (FDA) for a next generation test to assess ovarian cancer risk for women with a pelvic mass. The test guides physicians in treatment selection for ovarian mass surgery depending on malignancy risk.

Cell Medica, a cellular immunotherapy company, announced on March 18 that FDA granted Orphan Drug Designation to its cancer immunotherapy treatment under development for Epstein-Barr virus positive non-Hodgkin lymphomas. The company also announced the treatment of the first patient in a new clinical trial.

CPRIT's grant to UT Southwestern Medical Center (UTSW) for cancer genetic services for rural and underserved populations supports screenings for more than 86,000 women. The project identified five percent of the women screened as high risk for hereditary breast and ovarian cancer. These women now have options to reduce their risk of cancer. UTSW won the *Community Cancer Center Innovator* award in 2013 for work on this project.

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Personnel Changes and Job Openings

CPRIT has 32 authorized full-time equivalent (FTE) positions, of which 30 are filled as of April 1, 2016.

- Chief Scientific Officer Dr. James "Jim" Willson started work on March 1. His first major task was to oversee the Academic Research Program's seven peer review meetings held in Dallas March 9-16. Dr. Kripke attended the first week of panel meetings with Dr. Willson to help him transition into his new role. I also attended the peer review panel meetings held on March 15 and 16.

- Adriane Natal started March 15 in the role as executive assistant.

- David Escamilla, Grant Compliance Specialist, accepted a position with the Texas Veterans Commission effective March 31. The Grant Compliance Specialist position is posted and remains open through April 15.

- We extended a job offer to fill the vacant Grant Accountant position but the candidate ultimately declined the offer in late March due to unforeseen family issues. We will repost the position.

- Michael Brown, Program Manager for Academic Research resigned to take a position at M.D. Anderson effective April 1. The Program Manager position is posted and remains open through April 29.

Legislative and Related Briefings

- Kristen Doyle, Heidi McConnell and I met with staff from three legislators in March: Lieutenant Governor Patrick (March 1); Senator Bettencourt (March 24); and Senator Schwertner (March 30). We updated them on CPRIT's activities.

- Drs. Garcia, Willson and I met with State Representatives Kyle Kacal and Ken King on March 29 at their request concerning the KK125 Ovarian Cancer Research Foundation. The representatives established the foundation to honor their mothers, both of whom recently succumbed to ovarian cancer. Texas Medical Association staff also attended the meeting. Most of the discussion focused on compassionate care legislation and the CA-125 test. The CA-125 test may be used to detect early signs of ovarian cancer in women with a very high risk of the disease.

- Jeff Hahn and I met with Evan Smith, CEO and Editor-in-Chief of *The Texas Tribune*, on March 22 to update him on CPRIT activities and discuss a potential cancer panel for the big annual "Tribfest" conference scheduled for September 23-25, 2016, in Austin.

- Kristen Doyle, Cameron Eckel and I met with members of the Texas Cancer Partnership (cancer and bio-life sciences industry advocacy representatives) on March 3 to update them on CPRIT activities.

Strategic Planning

Broad discussions concerning programmatic and operational planning for the second half of CPRIT's grant-making life began in February and intensified in March. The current work group consists of CPRIT senior staff and Dr. Bill Rice representing the Oversight Committee. Jeff Hahn of Hahn Public Communications, CPRIT's communications contractor, serves as our facilitator. This effort is separate but related to the state mandated biennial strategic plan, which is expected to be due in June. I will continue to update the Oversight Committee on the status of this project.

Executive Management Training

In consultation with Oversight Committee members Ned Holmes and Dee Margo, Kristen Doyle, Heidi McConnell and I are investigating options for senior staff management training. Two executive training contractors have been identified that may be able to provide the desired training. Any training agreement must comply with state contracting requirements. Depending upon the cost, extent of training and use of a non-state agency contractor, Oversight Committee approval at the May 18, 2016, OC meeting may be required. If the contract is for more than $15,000, the Governor's Office must also approve the contract. We will have more information for the Oversight Committee on this project over the next few months.

Grantee Training Webinar

CPRIT staff conducted a grantee training webinar on March 30 for more than 300 grantee staff. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. Grantees also had the opportunity to ask questions during the two-hour training webinar. The training outreach is part of CPRIT's efforts to address compliance issues early. Grantees that attended the webinar fulfilled the administrative rule requirement for annual compliance training.

Compliance Program Update

Submission Status of Required Grant Recipient Reports

A delinquent report is produced by CPRIT's grant management system (CGMS) each week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT typically has 530+ grants that are either active or wrapping up grant activities and receives approximately 570 grantee reports each month.

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On-Site Reviews

Grant compliance staff performed three on-site reviews during the month of March covering two Prevention grants and one Product Development Research grant. No findings were identified during these reviews. On-site reviews typically include an examination of the grantee's financial and administrative operations, procurement and inventory procedures, personnel policies and

procedures, payroll and timesheet policies, travel policies and records, and single audit compliance.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in state awards in the grantee's fiscal year must submit a single independent audit, a program specific audit, or an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the grantee's fiscal year. Over the last two months, eight grantees submitted the appropriate documentation to fully remediate audit findings. There are currently no grantees with outstanding audit findings. Grant compliance specialists are working with two grantees regarding delinquent audit reports. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

Grantee Training & Support

CPRIT staff conducted a new grantee training for Coastal Bend Wellness Center in Corpus Christi on March 9. In addition to a brief overview of CPRIT's history and mission, the training covered grantee reporting requirements, an overview of the compliance program, and a hands-on navigation of CPRIT's online grants management system. CPRIT staff also conducted a grantee training webinar on March 30, with over 300 grantee staff in attendance. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process.

Academic Research Program Update

FY 2016 Cycle 2 Academic Research Applications and FY 2017 Cycle 1 Competitive Renewal Applications Under Review

Peer review panels met in Dallas March 9 – 16 to review more than 200 proposals. The proposals under review were submitted last October in response to requests for applications (RFAs) for High Impact High Risk Grants, Core Facilities Support Awards, Multi-Investigator Research Awards, and Core Facilities Support Awards for Competitive Renewals (Cycle 17.1). The seven peer review panels recommended 39 applications to the Scientific Review Council (SRC), including four Cycle 17.1 Core Facilities competitive renewal applications.

The SRC met March 29 to review the 35 pending recommendations for Cycle 16.2 (High Risk High Impact, Core Facilities, and Multi-Investigator awards). The chair of the SRC sent the council's recommendations for Cycle 16.2 to the presiding officers of the Oversight Committee and Program Integration Committee (PIC) on April 1. The PIC will meet May 3 to consider the recommendations in preparation for the May 18 Oversight Committee meeting.

The SRC plans to discuss the four Cycle 17.1 Core Facilities competitive renewal applications recommended by the review panels for awards at a meeting held after August 31. Any recommendations are expected to come to the Oversight Committee for approval at the November meeting

FY 2017 Cycle 1 Academic Research RFAs Released February 19

The Academic Research program released RFAs for Cycle 17.1 on February 19, 2016. These RFAs include Research Training Awards, untargeted Individual Investigator Research Awards, Individual Investigator Research Awards for Cancers in Childhood and Adolescents, Individual Investigator Research Awards for Prevention and Early Detection, Individual Investigator Research Awards for Computational Biology, and Early Translational Research Awards.

CPRIT is accepting applications March 21 through May 19, 2016. Peer review panels will meet in September. Award recommendations are expected to be considered at the November 2016 Oversight Committee meeting.

FY 2016 Cycles 7 – 9 Recruitment Applications Reviewed by SRC

Five applications were submitted in response to RFAs released for Recruitment Cycle REC 16.7. All five were reviewed by the SRC on February 11, 2016. No applications were recommended for funding.

Five applications were submitted in response to RFAs released for Recruitment Cycle 16.8. All five were reviewed by the SRC on March 24, 2016. The SRC recommends three applications for awards totaling $4,823,067. The recommendations have been submitted to the PIC and are scheduled to be considered at the May Oversight Committee meeting.

Nine applications were submitted in response to RFAs released for Recruitment Cycle 16.9. No applications were administratively rejected. The nine applications will be reviewed by the SRC in April, and depending on available funding, may come to the August 2016 Oversight Committee meeting for approval. The total request for these applications is $22 million.

Product Development Research Program Update

FY 2016 Cycle 1 Product Development Research Applications - Due Diligence Review

In December, the Product Development Research program panels recommended five applications for due diligence review. The business/regulatory due diligence and intellectual property reviews were completed and provided for Product Development Review Council (PDRC) consideration in March. The PDRC recommended two of the projects for awards after discussing the due diligence reviews at its March 21 meeting. The PIC and Oversight Committee will consider the recommendations in May. The total amount requested by the two recommended applications is $36,833,000.

FY 2016 Cycle 2 Product Development Research Applications Under Review

CPRIT released requests for Texas Company and Company Relocation applications in December. Thirty-two applications were submitted, making this among our largest submission pools. CPRIT will hold the first review panel meetings in early April to select the companies that will be invited for in-person presentations. Award recommendations from this cycle are expected to be considered by the Oversight Committee in August or September.

Product Development Strategy

We have been assessing CPRIT's investment policies and Product Development program strategy to identify opportunities to optimize CPRIT's impact. Four specific investment policies will be discussed with Product Development Research Subcommittee and other stakeholders over the next several months:

- Texas Location Criteria - CPRIT-funded companies must be located in Texas, but applicants and reviewers seek more guidance from CPRIT regarding issues related to virtual companies, company personnel located outside of Texas, and running clinical trials out of state. A set of objective criteria has been proposed for discussion.

- Stage of Development – CPRIT Product Development research awards currently support most stages of drug development. A recommendation has been developed to focus investing in the company formation through clinical proof-of-principle stages.

- Sector Specific Investing – CPRIT Product Development research awards support research and development associated with several relevant sectors including drugs, diagnostics, devices and tools. The majority (85%) of CPRIT's Product Development

research award funds support drug development. To highlight CPRIT's willingness to invest in other sectors, the use of targeted RFAs has been discussed.

- Repeat Applications – Some CPRIT-funded companies are now applying for new CPRIT grants. CPRIT does not currently prohibit grantees from receiving more than one Product Development research grant. We will discuss whether it is advisable to make a policy change to limit grants to one per company.

Specific strategies to optimize CPRIT's impact have also been discussed:

- University Spinout Support - Supporting new company formation and launch conforms with our mission and Texas academic institutions have expressed interest in collaborating. More in-depth connections with institutions and further assessment will be required if this is of interest to the Oversight Committee.

- Equity Holdings - CPRIT holds equity in two companies and likely will have additional equity holdings in future. A specific proposal on equity holding strategy has been generated for discussion.

Mr. Lang developed a presentation on these issues for the Oversight Committee. He has met with most Oversight Committee members individually to answer questions and solicit input.

Prevention Program Update

FY 2016 Cycle 2 Prevention Applications – Under Review

Six Requests for Applications were released on September 24, 2015. Forty-four applications were received by March 3, more than doubling the number of applications received the previous cycle. Dr. Garcia and Ms. Magid visited several parts of the state over the past several months to encourage applications; some of these new applications are a direct result of those efforts. Peer reviewers are being invited to participate on review panels that will meet May 23-25 in Dallas. With the increase in volume, additional reviewers are being recruited. A webinar briefing for new and returning reviewers is scheduled for April 13.

FY 2017 Cycle 1 Request for Prevention Applications to be Released in April

RFAs for Cycle 17.1 are being revised and updated for release in April 2016. Applications will be due August 30 and will go to the Oversight Committee for consideration in February, 2017.

Other activities

- A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor.

- Quarterly reports due March 15 are being reviewed.

Communications Update

CPRIT Messages

- Communications staff are making plans for the event celebrating CPRIT's half-way point in awarding the $3 billion entrusted to it to fight cancer. CPRIT will host the event at the Capitol Extension Auditorium on May 17, 2016, at 1:00-3:30 pm. The three Chief Program Officers will report on the state of their programs including key metrics and signature discoveries to date. We will also showcase a select group of CPRIT grantees whose projects demonstrate significant progress towards our mission. Legislators, cancer advocates and the media will be invited to this event.

- Staff continues to prepare slides for legislative briefing materials as needed.

- CPRIT conducted a test of the Significance Project survey with a small sample of grantees. We are revising the survey based on those results and will mail out the updated version to a larger group of grantees.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

Operations and Finance (Contracts, RFPs, Audit)

Internal Audit

On March 31 Heidi McConnell, Kristen Doyle, Vince Burgess, Lisa Nelson, Therry Simien, and Michelle Huddleston met with Alyssa Martin and Daniel Graves of Weaver and Tidwell, CPRIT's outsourced internal audit firm. The meeting kicked off CPRIT's FY 2016 Internal Audit plan with four internal audits (Information Security, Commodity and Service Contracts, Revenue, and Cash Management) and two follow-up procedure audits (Grant Management and

Information Services) scheduled for this year. The fieldwork for the first audit begins the first week of May, and the fieldwork for the sixth audit ends the first week of August. The internal auditor will complete all audit work and reports by the end of FY 2016.

Procurement

- On March 4 CPRIT released the Conference Planning and Coordination Services Request for Proposal (RFP) for an event planner to assist with the 2017 CPRIT conference. The RFP is advertised in the state's Electronic State Business Daily for 30 days.

- The Texas Department of Information Resources (DIR) approved CPRIT's proposed statement of work related to the redesign of CPRIT's website. On March 29, CPRIT distributed the Website Redesign Request for Offer (RFO) to 29 DIR-approved vendors who are capable of providing these website services. The goal is to have a contract for approval by the Oversight Committee in May.

Upcoming Oversight Committee-related Meetings

The Oversight Committee will hold its next meeting on May 18, 2016, at 10:00 am in the Capitol Extension. **Please note that the start time of the May meeting is different from the February meeting.** The Oversight Committee voted to use the 10:00 start time as the standard going forward.

The dates and times for the upcoming May subcommittee meetings are listed below.

Board Governance –	May 5 at 10:00 am
Diversity –	May 6 at 10:30 am
Audit –	May 9 at 10:00 am
Prevention –	May 10 at 10:00 am
Scientific Research –	May 11 at 10:00 am
Product Development –	May 12 at 10:00 am
Nominations –	May 13 at 10:30 am

An agenda, call-in information and supporting material will be sent to the subcommittees one week prior to the meeting date.

*****

CPRIT has awarded **998** grants totaling **$1.496 billion**

- 158 prevention awards totaling $155.4 million
- 840 academic research and product development research awards totaling $1.341 billion

Of the $1.341 billion in academic research and product development awards,

- 30.7% of the funding ($411.6 million) supports clinical research projects
- 25.6% of the funding ($342.6 million) supports translational research projects
- 24.9% of funding ($334.2 million) supports recruitment awards
- 15.5% of the funding ($208.2 million) supports discovery stage research projects
- 3.3% of funding ($44.4 million) supports training programs.

CPRIT has 9 open Requests for Applications (RFAs)

- 3 Research Recruitment
- 6 Academic Research

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO: OVERSIGHT COMMITTEE MEMBERS

FROM: JAMES WILLSON, M.D., CHIEF SCIENTIFIC OFFICER

SUBJECT: ACADEMIC RESEARCH UPDATE

DATE: MAY 11, 2016

Summary

This memo provides an overview of Academic Research program activities since the last Oversight Committee meeting in February. Subjects include the status of applications under review and the recent meetings with the University Advisory Committee and the Advisory Committee on Childhood Cancer.

Academic Research Award Review Cycles

Academic Research Review Cycle 16.2 Review

Thirty-four of 200 submitted applications evaluated by the peer review panels in March were recommended by the Scientific Review Council (SRC) for a total of $81,773,066. These include six Core Facility Support Awards (CFSA), seven Multi-Investigator Research Awards (MIRA), and 21 High Impact/High Risk Awards (HIHR). The Program Integration Committee reviewed the rank ordered list of research applications submitted by the SRC and recommends that the Oversight Committee approve 27 proposals totaling $34,523,901. The Program Integration Committee elected to defer until the August meeting final award decisions on two Core Facilities and five Multi-Investigator proposals recommended by the Scientific Review Council.

Academic Research Review Cycles 16.7-16.9 Recruitment Review

During the third quarter of FY 2016, the SRC reviewed 14 Recruitment Awards for First Time Tenure Track Faculty and recommended six for a total of $10,823,067. Three Established Investigator and three Rising Stars applications were reviewed but none were recommended. The Program Integration Committee recommended the six First Time Tenure Track Faculty recruitment awards for Oversight Committee approval at the May 18 meeting.

Based upon historic data, we expect that the SRC will recommend an additional $20-30 million in recruitment awards during the final quarter of FY 2016. The SRC is scheduled to review 13 recruitment applications this month requesting a total of $44 million.

Academic Research Review Cycle 17.1 Request for Applications (RFAs)

Research RFAs for 17.1 were posted on February 19, 2016. Applications are accepted March 21 through May 19. The applications will be evaluated at peer review meetings in September, and

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grant recommendations will come to the November 2016 Oversight Committee meeting for approval. These RFAs include Research Training Awards, untargeted Individual Investigator Research Awards (IIRA), Individual Investigator Research Awards for Cancers in Childhood and Adolescents (IIRACCA), Individual Investigator Research Awards for Prevention and Early Detection (IIRAP), Individual Investigator Research Awards for Computational Biology (IIRACB), and Early Translational Research Awards (ETRA).

University Advisory Committee

The University Advisory Committee (UAC) met via teleconference on April 25, 2016. Mary Ann Ottinger Ph.D., Associate Vice Chancellor for Research, University of Houston System, has assumed the UAC chair and two new members have been appointed:

- Michelle C. Barton, Ph.D., from MD Anderson Cancer replaces Dr. Willson as the UT System representative
- Mike Blanda, Ph.D., replaces Dr. Bill Covington as the representative from the Texas State University System.

Wayne Roberts and I participated in the conference call. I presented my vision for the CPRIT Research Program portfolio and led a discussion of the UAC recommendations made in their 2015 annual report to the Oversight Committee. The Committee identified support for clinical trials research and development of outcome metrics to evaluate the success of CPRIT programs. The UAC plans a retreat in June to discuss an action plan to address these and other issues that will frame the Committee agenda for the next year.

Advisory Committee on Childhood Cancer (ACCC)

The ACCC met via teleconference on April 26, 2016. Wayne and I participated and provided updates on the impact of recent Core Facility Support and Investigator initiated RFAs that target Childhood Cancers. There were five Investigator Initiated Research Awards in Childhood Cancer awarded in FY 2016, and there was a robust response from the pediatric cancer community to the recent Core Facility Support RFA.

The conference call provided me the opportunity to share my vision for the CPRIT Research Program and to hear from the ACCC members their recommendations of mechanisms to further strengthen pediatric cancer research in Texas. ACCC members discussed several examples of the impact CPRIT has had on pediatric research and care. One notable example discussed was the PASSPORT for Care, a program supported by CPRIT's Prevention Program to provide survivors of pediatric cancer access to portable medical records and surveillance recommendations. This program is an example of a CPRIT supported collaboration that engages multiple institutions across Texas and developed best practices that are now being adopted outside Texas. The ACCC plans quarterly teleconference calls to advise CPRIT on opportunities to catalyze cooperative programs that leverage pediatric cancer expertise across Texas.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

To:	OVERSIGHT COMMITTEE MEMBERS
From:	MICHAEL LANG, CHIEF PRODUCT DEVELOPMENT OFFICER
Subject:	PRODUCT DEVELOPMENT UPDATE
Date:	MAY 12, 2016

Summary and Recommendation

This memo provides an overview of Product Development activities since the last Oversight Committee meeting in February. Subjects include status of applications under review, membership changes for the Product Development Review Council (PDRC), the business plan review process for Early Translational Research Awards, an update on my development of the Product Development Research program strategy, and a review on company-specific issues. The Product Development Research Program has two award recommendations to be considered at this meeting.

Product Development Application Review Process Updates

Product Development Review Cycle 16.1

Requests for applications for the FY 2016.1 review cycle were released August 3, 2015. CPRIT received 25 applications. Peer review took place at meetings on October 29-30, 2015 (peer review panel screening teleconference), December 1 and 3, 2015 (in-person presentations), and March 21, 2016 (due diligence review).

Of the 25 applications submitted in this cycle, 12 applicants were invited to make in-person presentations, of which five were selected for due diligence review. After consideration of the due diligence reports, the PDRC recommended two applications for grant awards. The Program Integration Committee unanimously approved including both companies on the list of proposed award recommendations provided to the Oversight Committee. Following the PIC's decision, I contacted both companies to negotiate proposed budgets. This communication was done pursuant to the CEO's waiver of the restriction on communication with grant applicants. After discussions, I was able to reduce the requested award amounts by nearly $3M. I will update the Oversight Committee on the proposed reductions at the meeting on May 18.

Product Development Review Cycle 16.2

Requests for Texas Company and Company Relocation applications were posted to CPRIT's website in December. Thirty two applications were submitted, making this among our largest submission pools. The screening teleconference was held April 7 & 8. Thirteen of the 32 companies were selected to be invited to present at the Peer Review meeting on May 10-12. Award recommendations from this cycle are expected to be considered by the Oversight Committee in August or September.

Product Development Review Council Membership

At the February Oversight Committee meeting, I notified you that CPRIT planned to add two new PDRC members: Dr. Robert Sarisky and Dr. Neil Spector. Dr. Sarisky has a PhD and MBA and is currently Vice President of Business Development for Johnson & Johnson Pharmaceutical Services Oncology division. Dr. Neil Spector is an Associate Professor of Medicine at Duke University and the Co-Director of Experimental Therapeutics Program at the Duke Cancer Institute. Although they will be new to the PDRC, both Dr. Sarisky and Dr. Spector have been valuable members of the CPRIT Product Development Research review panels. The new PDRC members started work March 1. Adding two members to the PDRC not only allows CPRIT to benefit from a wider scope of expertise but also increases the resources available to conduct progress and tranche reports.

Early Translational Research Awards (ETRAs) – Business Plan Review

The Oversight Committee approved 20 ETRA grants to Texas academic institutions in November 2014. The objective of an ETRA grant is to "bridge the gap between promising new discoveries achieved in the research laboratory and commercial development." Consistent with that objective, one of the program requirements for these ETRA grantees is to submit business plans along with their first year progress report. The process of developing a business plan for the CPRIT project is intended to confirm that the principal investigator is taking appropriate steps toward developing a valid commercial opportunity for the CPRIT-funded technology.

Product Development reviewers with business expertise will individually review the business plans and provide feedback to the ETRA grantees. We have received Business Plans from all active grants and the review process is underway. We anticipate having all business plans reviewed by end of May.

Company Connections

Since joining CPRIT late last year, I have met with nearly all of CPRIT's active Product Development Research Program portfolio companies, numerous prospective applicant companies, representatives of the key Texas research institutions, and attended health care industry conferences. The objective of these meetings has been to enhance relationships with the Texas bioscience industry, promote CPRIT and identify other opportunities for CPRIT's Product Development Research Program to support ecosystem development.

Product Development Review Process

We are collaborating with the PDRC on multiple initiatives to improve the product development review process. The first priority is to improve the quality and applicability of due diligence reports. A meeting with our third party review contractors was held to review and plan potential changes in report structure. Numerous improvement opportunities were discussed, and implementation is underway.

The RFA is being updated to incorporate PDRC and Oversight Committee input on various policy changes including:

- Highlighting CPRIT interest in funding all sectors that impact cancer care (therapeutics, diagnostics, devices etc.)
- Objective criteria defining Texas location
- Streamlining our investment policy to focus on preclinical and Phase I and IIA stages of development
- Clarifying our investment policy to avoid multiple awards to same firms.

Product Development Research Program Strategy

We have been assessing the Texas cancer research and product development landscape. The objective is to evaluate the Texas bioscience industry relative to other states. A key learning from this assessment is that compared to other states on a per capita basis, Texas falls behind in federal research funding, venture capital (VC) investment and startup efficiency. The investments CPRIT has made in both academic and product development research have made a significant impact in Texas, but there is still work to be done to increase the state's life sciences infrastructure.

A comprehensive analysis, including strategies to accelerate industry development, has been developed and presented to individual Oversight Committee members.

Strategies identified to date include:

- University Spinout Support - Supporting new company formation and launch is synergistic with our mission, and Texas academic institutions have expressed interest in collaborating. Preliminary discussion with major Texas research institutions indicates strong interest. More in-depth discussions with institutions and further assessment will be required to fully assess the viability of this idea.
- Early Company Support - CPRIT is sometimes the first major investor into a company. When this occurs the company would not have external investors providing business oversight, guidance and industry connections. Providing appropriate oversight to early stage companies will enhance their probability of success.
- Stage of development. –CPRIT has made awards to companies at all phases of the product development process. However, CPRIT impact is typically greater when we invest in early stage companies. Once a company has shown a new therapy has efficacy, valuation and funding options increase significantly. Prior to this milestone companies often struggle to obtain funding. Focusing product development research awards on early stage companies that are working toward demonstrating efficacy maximizes our impact on cancer care and Texas economic development.

Equity Ownership Policy

CPRIT investments have generated asset holding which have monetary value. We own stock in three companies, and the royalty streams due us have value. Either the stock or royalty rights could be held long term or monetized at any time.

CPRIT currently holds equity in three companies: Cell Medica, Mirna Therapeutics, and Codiak BioSciences. (Codiak BioSciences is not a CPRIT-funded company; CPRIT's equity ownership results from the revenue sharing agreement with MD Anderson, who licensed work done by CPRIT recruit, Dr. Raghu Kalluri, to Codiak.) Both Cell Medica and Codiak are privately held; Mirna's equity is owned via publicly traded stock. The number of equity positions held by CPRIT may rise as our product development portfolio grows and an increasing number of CPRIT-funded companies engage in follow-on financings, acquisitions or other transactions. Obviously, if CPRIT is interested in taking equity in addition to/in place of CPRIT's royalty-based standard revenue sharing terms this will increase our equity holdings.

A standard policy to manage CPRIT equity holdings is under development. Advantages of a standard policy to manage equity ownership include efficiency, transparency, and minimizing disruption to the portfolio company (particularly important when CPRIT has significant holding). For example, it may be advantageous that, as a general policy, CPRIT hold shares of a private

company until the company is acquired or is publically traded via an initial public offering (IPO). For publically traded stock owned by CPRIT, CPRIT may want to adopt a pre-scheduled stock sales policy. Pre-scheduling the stock sale and publicly announcing it provides transparency and avoids adversely impacting the market.

CPRIT is planning to meet with the Texas Treasury Safekeeping Trust Company, a special purpose trust company whose mission is to preserve and grow the State's financial resources by competitively managing and investing them in a prudent, ethical, innovative and cost-effective manner while focusing on client needs. We hope to learn more about their policies and processes and assess how they may be applicable to our portfolio of assets. An equity ownership policy proposal will be developed for Oversight Committee review and approval.

Company Specific Issues

- Ruga contract has been initiated.
- Vermillion contracted has been initiated. The company may be interested in an equity based return, in lieu of our standard royalty rates, and indicated they would assess and generate a proposal.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

May 12, 2016

Oversight Committee Members,

Pursuant to 25 T.A.C. § 703.7(j), I request that the Oversight Committee approve authority for CPRIT to advance grant funds upon execution of grant contracts for two companies that will be considered for Product Development grant awards at the May 18, 2016, Oversight Committee meeting. The companies have been recommended for grant awards by the Program Integration Committee (PIC). The Oversight Committee will consider the PIC's recommendations at the May 18, 2016, Oversight Committee meeting.

Although CPRIT disburses the majority of grant funds pursuant to requests for reimbursement, CPRIT may disburse grant funds in advance payments consistent with the General Appropriations Act, Article IX, § 4.03(a). Typically, the grant amount to be paid in advance is based upon the project year budget or tranche amount. All grant recipients, including those that receive advance payment of grant funds, are required to submit quarterly financial status reports that are reviewed and approved by CPRIT's financial staff. Failure to submit the financial status reports on a timely basis will result in forfeiture of reimbursement for expenses for the quarter and may result in grant termination and repayment of grant funds.

Advance payment of grant funds are needed because compound synthesis and pre-clinical trial contracts typically require substantial upfront payments. The cost structure for these contracted services is highly front loaded. Hence service providers require substantial upfront payments.

Sincerely,

Wayne R. Roberts,
CPRIT Chief Executive Officer

P.O. Box 12097 Austin, TX 78711 (512) 463-3190 Fax (512) 475-2563 www.cprit.state.tx.us

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PHD, CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	PREVENTION PROGRAM UPDATE
DATE:	MAY 9, 2016

FY 2016 Cycle 2 Prevention Applications – Under Review

Six Requests for Applications were released on September 24, 2015. Forty-four applications were received by March 3, more than doubling the number of applications received the previous cycle. Ramona Magid and I visited several parts of the state over the past several months to encourage applications; some of these new applications are a direct result of those efforts. Assignments have been made to peer reviewers. The review meeting will be held May 23-25 in Dallas. A webinar briefing for new and returning reviewers was conducted April 18.

FY 2017 Cycle 1 Request for Prevention Applications to be released in May

RFAs for Cycle 17.1 are being revised and updated for release in May 2016. Applications will be due August 30 and will go to the Oversight Committee for consideration in February 2017.

Other activities

- Geographic coverage: In the quarterly reports due March 15, some grantees reported serving more counties than originally proposed. One grantee reported serving people from the two counties (Hamilton and Coryell) that had not previously been covered by direct services. While the program has always included web based and other projects serving all counties in the state, this is the first time the program can claim, that at some point in the program's history, people in every county have had a direct service.
- A complete redesign of the grantee quarterly reports is underway with SRA, CPRIT's grant management contractor. The revised report will be tested with a few grantees prior to its release.

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Statistics as of May 2016

Achievements: Prevention

- Over 1. 3M education and 1.5M clinical preventive services provided, including:
  - screenings/diagnostics for breast, cervical and colorectal cancer.
  - Prevention Vaccinations
  - Tobacco cessation services
  - Genetic testing and counseling
  - Survivorship services

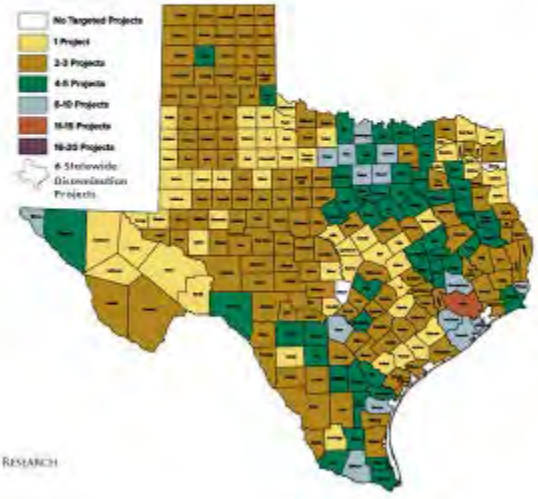
2.8 Million
Prevention
Services to Texans

Every $1 spent through CPRIT for screening/prevention leads to $22 in treatment cost savings, preserved productivity, and other economic benefits through earlier detection of cancers.

Cancer Prevention & Research Institute of Texas — As of May 2016

Geographic Coverage

Counties Served by CPRIT Prevention Projects
62 Active Projects – May 2016



Cancer Prevention & Research Institute of Texas

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	REBECCA GARCIA, PH.D. CHIEF PREVENTION AND COMMUNICATIONS OFFICER
SUBJECT:	COMMUNICATIONS UPDATE
DATE:	MAY 18, 2016

The following report provides an overview of the agency's communications activities from Feb. 17, 2016 through May 18, 2016.

EARNED MEDIA

The communications team worked with and pitched individual publications and reporters to secure positive coverage for CPRIT, including coordinating an interview with BioNews Texas to highlight CPRIT's dedicated conference room in honor of Carson Leslie's memory. The same article mentions the work CPRIT and the Carson Leslie Foundation are doing to invest in the fight against childhood and pediatric cancer in Texas.

The agency also conducted media outreach for the Halfway Point press briefing on May 17, 2016. As a result, CPRIT secured an interview with the Houston Chronicle and other key publications. The coverage will be represented in the August communications update.

Grant Awards Announcement: Following the Oversight Committee's approval, on Feb. 17, 2016, CPRIT distributed a press release to and pitched local, regional and national media announcing the awarding of seven academic research grants, which resulted in some of the coverage represented below.

Coverage: (Feb. 6, 2016 – May 2, 2016)

- 5 articles featured CPRIT
- 47 additional articles mentioned CPRIT (stories primarily focused on work of grantees)

Coverage Highlights: (see clipped articles following report)

- Feb. 17, 2016, *Houston Business Journal*, Houston is the Big Winner in Latest Texas Cancer Research Funding Round
- Feb. 18, 2016, *D Healthcare Daily*, UT Southwestern Gets $2 Million Recruitment Grant to Lure California Researcher
- Feb. 19, 2016, *Houston Chronicle*, MD Anderson, Baylor Receive Massive Grants

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- Feb. 19, 2016, *Austin American-Statesman*, University of Texas Hires Cancer Researcher With $6 Million Grant
- Feb. 23, 2016, *The Daily Texan*, Grant Brings New Professors and Technology to Campus to Further Cancer Research
- April 15, 2016, *The Cancer Letter*, Former MD Anderson Provost Reflects on "Brief, Painful Episode"
- April 18, 2016, *BioNews Texas*, CPRIT Honors Fundraising Work of Carson Leslie Foundation with Commemorative Plaque

CPRIT Messages

- Communications staff are making plans for the event celebrating CPRIT's halfway point in awarding the $3 billion entrusted to it to fight cancer. CPRIT will host the event at the Capitol Extension Auditorium on May 17, 2016, from 1:00-3:30 pm. The three Chief Program Officers will report on the state of their programs including key metrics and signature discoveries to date. We will also showcase a select group of CPRIT grantees whose projects demonstrate significant progress towards our mission. Legislators, cancer advocates and the media will be invited to this event.

- CPRIT conducted a test of the Significance Project survey with a small sample of grantees. The survey was revised and sent out to a larger group of grantees, with a May 5 deadline.

- 2017 Conference: Planning for the 2017 Conference has begun with the selection of meeting planning services. Swift Solutions, the vendor that assisted us with the 2015 conference, was awarded the contract. The next step is to release an RFP for a hotel venue. The plan is to present the hotel contract to the Oversight Committee in August for consideration.

- Communications staff worked with IT and the procurement staff to issue the RFP and evaluate the applicants for the Website redesign services. That contract is to be presented to the Oversight Committee in May for consideration.

- Staff continues to prepare legislative briefing materials as needed.

Social Media

Communications staff continues to use social media outreach, including Twitter and Facebook, to publicize CPRIT-generated content along with news and information about and from grantees, advocates and other trusted sources.

HOUSTON BUSINESS JOURNAL

Houston is the big winner in latest Texas cancer research funding round

W. Scott Bailey

Feb 17, 2016,

The Cancer Prevention and Research Institute of Texas awarded $26 million in new grants on Feb. 17 to institutions in three cities in the Lone Star State.

The big winner in this CPRIT funding round is the University of Texas MD Anderson Cancer Center in Houston, which has been awarded $14 million to recruit three new cancer scientists. The Bayou City institution is receiving $6 million to recruit Xiaodong Cheng from the Emory University School of Medicine and a similar amount to recruit Filippo G. Giancotti from Memorial Sloan Kettering Institute for Cancer Research.

MD Anderson is also receiving $2 million to recruit Traver Hart from the University of Toronto.

Houston's Baylor College of Medicine has been awarded $4 million to recruit cancer researcher Bing Zhang from Vanderbilt University's School of Medicine.

Austin is also cashing in on the CPRIT funding. The University of Texas has been awarded $6 million to recruit Daniel J. Leahy from the Johns Hopkins School of Medicine.

In Dallas, the University of Texas Southwestern Medical Center will get $2 million from CPRIT to recruit Luke Gilbert from the University of California at San Francisco.

Since its inception, CPRIT has awarded 110 recruitment grants totaling more than $334 million.

http://www.bizjournals.com/houston/news/2016/02/17/houston-is-the-big-winner-in-latest-texas-cancer.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+industry_22+%28Industry+Education%29

DALLAS/FORT WORTH HEALTHCARE Daily
THE BUSINESS OF HEALTHCARE IN NORTH TEXAS

UT Southwestern Gets $2 Million Recruitment Grant To Lure California Researcher

by Matt Goodman *02/18/2016*

UT Southwestern Medical Center landed a $2 million state grant to recruit a doctor from the University of California, San Francisco who will be placed on a tenure track should he accept the position.

Dr. Luke Gilbert, a postdoctoral scholar of cellular molecular pharmacology at the UCSF School of Medicine, was recommended to join UT Southwestern by the Cancer Prevention and Research Institute of Texas, better known as CPRIT. He is one of six researchers the state pulled into its orbit using $26 million in grants.

None have yet agreed to come on, but the institutions—UTSW, Houston's MD Anderson, UT Austin, and Baylor College of Medicine—have the state's blessing to negotiate using the amount for the grants.

http://healthcare.dmagazine.com/2016/02/18/ut-southwestern-gets-2-million-recruitment-grant-to-lure-california-researcher/

HOUSTON CHRONICLE

MD Anderson, Baylor receive massive grants

Funds will be used to recruit top scientists for cancer research

By Todd Ackerman February 19, 2016

Texas' state cancer agency this week awarded M.D. Anderson Cancer Center and Baylor College of Medicine $16 million to help recruit three star scientists.

The Houston institutions dominated the latest round of Cancer Prevention and Research Institute of Texas grants, which focused solely on the recruitment of top researchers. The grants have received less attention than those the agency gives for research but may be a bigger boon to the state, luring world-class scientists, "rising stars" and promising first-time, tenure-track faculty members to Texas institutions.

"We continue to assemble a critical mass of expertise in cancer research in Texas through the recruitment of top scientists who have demonstrated academic excellence, innovation and potential for impact," Wayne Roberts, CPRIT's chief executive officer, said in a news release. "These grants have put Texas on the map as a destination for the cancer researchers in the world."

The recruitment program has now brought 105 scientists to Texas, totaling more than $340 million. Baylor and M.D. Anderson got $18 million of the $26 million allocated Wednesday.

CPRIT is the state's 10-year, $3 billion assault on cancer, launched in 2009, after voters approved a 2007 bond issue to fund it. The agency has awarded more than 800 academic research grants totaling $1.05 billion and helped bring 110 cancer researchers to Texas. In all, it has given out nearly $1.5 billion to different Texas institutions.

The agency rebooted in fall 2003, after scandals uncovered in 2012 and early 2013 threatened its continued existence. The scandals, involving the mismanagement of three grants totaling $56 million, resulted in the agency being shut down for 10 months and the Legislature's passage of a reform bill that removed the entire governing board and instituted additional safeguards to prevent abuse from occurring again.

The new awards included two $6 million grants to recruit top-tier scientists to M.D. Anderson - one for Ziaodong Cheng, a structural biologist at Emory University; and one for Dr. Filippo Giancotti a cell biologist at Memorial Sloan Kettering Cancer Center. The cancer center also was awarded a $2 million, first-time, tenure-track grant to recruit a post-doctoral scholar in genetic engineering at the University of California at San Francisco.

Baylor was awarded a $4 million grant for the recruitment of Bing Zhang, a "rising star" in molecular biology at Vanderbilt School of Medicine.

The University of Texas-Austin, with a $6 million recruitment grant for a top-tier scientist, and UT Southwestern Medical Center at Dallas, with a $2 million grant for a first-time, tenure-track scientist, received the other awards.

Only the scientist targeted by UT-Austin has accepted his offer. The remaining three scientists are still in negotiations with the universities.

http://www.houstonchronicle.com/news/houston-texas/houston/article/MD-Anderson-Baylor-receive-massive-grants-6843832.php

Austin American-Statesman

University of Texas hires cancer researcher with $6 million grant

Marty Toohey Feb. 19, 2016

The University of Texas will bring in a new cancer researcher to head its Department of Molecular Biosciences using a grant from the state's $3 billion cancer-fighting initiative.

The $6 million grant will go to hiring Daniel Leahy, a researcher at the Johns Hopkins University School of Medicine, and purchasing a cyro-electron microscope that helps biologists to see the inside of a cell in especially high resolution. Leahy has researched the effectiveness of different therapies for lung and breast cancers, according to a statement from the university.

The grant came from the Cancer Prevention and Research Institute of Texas.

Daniel Leahy

http://www.statesman.com/news/news/local/university-of-texas-hires-cancer-researcher-with-6/nqSr3/

THE DAILY TEXAN
Serving the University of Texas at Austin community since 1900

Grant brings new professors and technology to campus to further cancer research

BY JANELLE POLCYN February 23, 2016

Through funding from the Cancer Prevention and Research Institute of Texas, two established investigators and the latest in structure microscope technology are being brought to UT.

In January, Thomas Yankeelov, a professor of cancer research at Vanderbilt University, and Daniel Leahy, a biophysics professor at the Johns Hopkins University School of Medicine, were brought to UT to teach classes, continue their research and contribute their experience in cancer research to three colleges within the University.

Yankeelov is working with the Dell Medical School and the Cockrell School of Engineering, and Leahy is working with the College of Natural Sciences.

"The outstanding colleagues and resources available at UT will allow my lab to pursue new and exciting avenues of research," Leahy said. "We research the molecular mechanisms by which specific growth factors trigger cells to grow and divide. Understanding how these molecules work in normal and disease states is both extremely interesting and likely to guide design of anticancer therapies."

In conjunction with the recruitment of Leahy, the College of Natural Sciences purchased a cyro-electron microscope, a tool that allows scientists to look at protein structures. The tool will compliment and expand the University's research, including Leahy's, Dean Appling, aassociate dean for research and facilities of the College of Natural Sciences, said.

"[This new microscope] allows visualization of molecules in various activity states," Leahy said. "We look at the structures of receptors for [multiple] factors to learn what structural changes … are linked to cell growth and division."

Leahy's research will focus on lab work with cells using the new microscope, while Yankeelov will be working with the patient population in the clinical settings of hospitals in the Austin area.

"The past decade has witnessed an enormous increase in our knowledge of cancer on multiple scales, yet the outcome for many cancers has not improved," Yankeelov said. "The overall goal of our research program is to develop tumor forecasting methods by integrating advanced imaging tech with other patient-specific data, to build predictive multi-scale biophysical models of tumor growth to optimize therapy on a patient-specific basis."

Yankeelov has already started collaborating with research institutes on campus and community healthcare centers around the city.

"It is important to note … the [Dell Medical School] will provide us with the opportunity to take our methods to a large patient population, and the Institute for Computational Engineering and Sciences will allow for a dramatic expansion of our efforts at computational model of tumor growth and treatment response," Yankeelov said.

http://www.dailytexanonline.com/2016/02/23/grant-brings-new-professors-and-technology-to-campus-to-further-cancer-research

THE CANCER LETTER

Former MD Anderson Provost Reflects on "Brief, Painful Episode"

By Raymond DuBois Apr 15, 2016

Over the past several weeks, The Cancer Letter has been running a series of articles that report on a past conflict between people at The University of Texas MD Anderson Cancer Center and Nobel Laureate Al Gilman, who led the scientific review teams of the then newly formed Cancer Prevention and Research Institute of Texas.

At the time of the controversy, I was the founding provost and executive vice president at the MD Anderson Cancer Center, a position I enjoyed greatly. While I have no desire to revisit this brief, and somewhat painful episode in my academic career, I have been written into Goldberg's Texas drama as an important bit player and therefore feel compelled to go on record and provide my view of the story.

First and foremost, I was thrilled to be involved in the early days of CPRIT when the agency was finding its sea legs in terms of funding cancer research that would have a transformational impact. Our president at the time, John Mendelsohn, wanted MD Anderson to compete well for the CPRIT funds and use those funds to advance the cause against cancer. I introduced myself to Al Gilman shortly after he was appointed and let him know that I would take the lead in organizing the CPRIT applications from MD Anderson and offered to do anything I could to help him in the process.

Over the next several months we came to know and respect each other and communicated several times each month. Dr. Gilman basically wanted CPRIT to support the highest quality science and avoid an avalanche of less-than-stellar applications that might clog the system. The scientific advisory committee he assembled was one of the finest in the nation—in fact, world-class—and the system he set up worked extremely well. CPRIT funded, and continues to fund, top-notch cancer research that makes a difference in the prevention and treatment of this insidious disease.

When Dr. Gilman decided to resign from the organization, I was still at MD Anderson and, at one point, was even approached about considering replacing him as CPRIT's chief scientific officer. However, by that time I had accepted a position as the executive director of the Biodesign Institute at Arizona State University, so I was not an appropriate candidate to lead that organization.

Fortunately for all involved, Margaret Kripke stepped in and was able to get CPRIT back on track. She was a much better choice than I would have been. CPRIT needed a strong scientist with impeccable credentials, who could "herd all the cats," negotiate through the politics, and return the focus to the intractable issues of cancer – which is exactly what Dr. Kripke did.

On the other hand, I remained involved with CPRIT and spent the past three years serving as a scientific advisor for the commercialization grant review committee. I am pleased to have helped support the funding of some truly groundbreaking commercialization grants which will have an economic impact on the state of Texas.

Which brings me back to my original point. As Paul Goldberg revealed through his tape recorded phone interview with me, the CPRIT controversy was a brief, awkward blip in my career. Taking the long view, it's rare that anyone in academic medicine doesn't hit a rough patch, and it pales in comparison to the kinds of rough spots cancer patients deal with all the time.

Plus, I was offered an outstanding opportunity to lead the Biodesign Institute at ASU, which was a unique and mind-broadening experience that allowed me to work with scientists from a wide range of disciplines—medicine, biology, chemistry, physics, botany, astronomy, medicine, evolutionary medicine, nanotechnology, bioengineering, nanocrystallography, biomimicry, vaccinology, bioinformatics—all trying to find answers to the most intractable issues in health, sustainability and biosecurity now facing our planet. I benefited scientifically and professionally from having had this experience.

Recently, I accepted a new position as Dean of Medicine at the Medical University of South Carolina and am thrilled to be overseeing the training of the next generation of doctors, clinical scientists and others in a region of the country important to me and my family, and where I believe I can genuinely make a positive impact. I am very happy with how my career has unfolded, and I have even been able to stay in touch with my friends and colleagues at MD Anderson, Vanderbilt and Hopkins.

The Cancer Letter's decision to publish a historical perspective between Al Gilman and CPRIT has given me a chance to contemplate a few things. First, I'm glad this will give me the opportunity to properly eulogize Al Gilman. He was brash, bombastic and brilliant. He also established an elegant structure for stimulating creative cancer research in Texas, which continues to propel the field forward in unprecedented ways.

Second, I want to state that MD Anderson's clinicians and physician-scientists are among the best in the world. I still call upon them regularly for referrals when patients present with complex cancer diagnoses. To a person, they have always taken my calls and genuinely care about the overwhelming dilemmas these patients confront. I am especially thankful for their recent superb care of one of my family members.

Also, I must acknowledge the unsung heroism of Margaret Kripke. She realized CPRIT's importance in the fight against cancer, ignored all the background noise and kept the organization afloat and operating successfully. Not many people would have been able to achieve as much.

And finally, I want to express my pride in the people from my home state of Texas. They courageously voted to fund a then-amorphous cancer research organization with $3 billion of their hard earned money in the hope it might crack the cancer code and lead to better treatments. Their faith in CPRIT weathered the ups and downs of several extraneous issues that threatened to derail it. It took real guts to continue to support the initiative.

In fact, CPRIT is alive and well today because even when things got tough, people like Al Gilman, Margaret Kripke and the citizens of Texas refused to back down. In the end, it's cancer patients around the world who will benefit from their foresight, determination and resilience.

Ironically, cancer is the culprit responsible for taking Dr. Gilman's life. I have to believe that some of the research supported by CPRIT under his watch will result in more effective treatments and early detection for pancreatic cancer that will affect generations to come. Part of this future success will come from the highest scientific standards he so vigorously supported.

BIO News Texas

CPRIT Honors Fundraising Work of Carson Leslie Foundation with Commemorative Plaque

CHARLES MOORE APRIL 18TH, 2016

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Last July, The Cancer Prevention and Research Institute of Texas (CPRIT) announced it would honor the legacy of Carson Leslie and the Carson Leslie Foundation by naming a conference room in its new office suite in the William B. Travis State Office Building in Austin, Texas, after Carson Leslie.

The Texas-based nonprofit Carson Leslie Foundation raises funds for pediatric cancer research and provides encouragement to teens stricken with disease. It was founded by its executive director, Annette Leslie, after losing her son Carson, 17, to medulloblastoma, a brain and spine cancer, on Jan. 12, 2010.

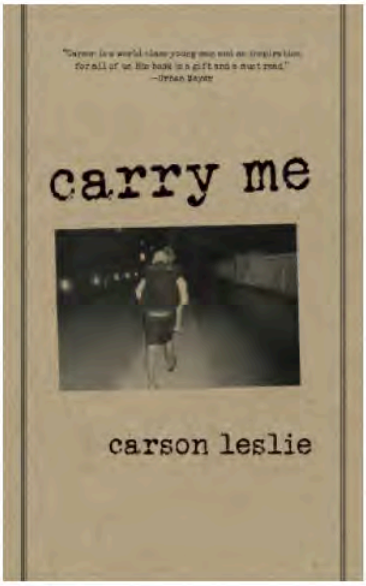
CLF CARSON LESLIE FOUNDATION because kids can't fight cancer alone

Leslie, whose background is in teaching, sales, and event coordination, is a graduate of Southwest Texas State University with a bachelor's degree in journalism and speech communication, and is a member of CPRIT's Advisory Committee on Childhood Cancers. Honoring her promise to Carson to continue the fight against pediatric cancer, she gives speeches, calls legislators on state and federal levels, promotes sales of Carson's book, "Carry Me," and serves as co-chairman of The Carson Leslie Foundation. She previously served as chairman of a local pediatric cancer organization's annual golf tournament auction that exceeded its fundraising goal, and is a talented photographer. Annette Leslie and her husband Craig live in Dallas. They have another son, Carson's older brother, Craig.

In the years since it was established, the Carson Leslie Foundation has worked to help children and teenagers fight cancer by establishing partnerships with institutions such as CPRIT, and by honoring Carson's memory.

"We named CPRIT's conference room after Carson to honor his memory and to inspire us with a tangible reminder of the courage, strength, and hopefulness he showed in his fight against cancer. CPRIT has made childhood cancer a priority, funding 63 grants totaling almost $69 million. Our increased grant support is intended to accelerate progress for prevention and research of pediatric and adolescent cancers, and to help Texas become a global leader in childhood cancer research," said CPRIT CEO Wayne Roberts in a release provided to *BioNews Texas*.

Carson Leslie was diagnosed with medulloblastoma, a brain tumor, at the age of 14 in 2006. He shared his fight against cancer in his book, "Carry Me," which was published six days before he died, and which he hoped would offer encouragement and strength to other young cancer patients. He asked his family to make sure that researchers study the tumors in his brain, "because if those tumors can help some kid not die from cancer like I am, I'd like that, it's hard to have cancer."



In "Carry Me," Carson wrote, "My name is Carson Leslie, and I have been battling brain and spine cancer for the past three years. I love sports, babies and Mexican food.

"I have written a book to give a voice to the teenagers and children who have cancer but are unable to express how such an illness affects their personal, social, physical and emotional life. I want others to understand how to be a better friend to someone he/she knows that has a life threatening disease. Even though every day of my life is a battle, I have learned that God is always there to lift me up, and I live each day as if it were the Day of Judgement.

"I believe my story will give readers a new perspective on the importance of how words and/or actions affect those around them. I wish to make a difference, and I know others my age want to do the same. Maybe after they read my book they will discover how to live the struggle."

Carson requested that his tombstone be inscribed with the Bible verse Joshua 1:9 — "Have not I commanded thee? Be strong and of a good courage; be not afraid, neither be thou dismayed: for the Lord thy God is with thee whithersoever thou goest" — explaining: "it is not just my cancer verse, it's my life verse and no matter how long I live, I want it written on my tombstone so if people visit my grave, they will know how God got me through my troubles in life."

The commemorative plaque that now hangs in The Carson Leslie Conference Room reads, in part, CARSON ROBERT LESLIE, July 6, 1992 – January 12, 2010, "I can either go around mad and sad, or go around living with the strength and courage that comes from God and from the people he puts around me". ~ Carson Leslie

CARSON ROBERT LESLIE
July 6, 1992 - January 12, 2010

"I can either go around mad and sad, or go around living
with the strength and courage that comes
from God and from the people he puts around me."

Carson was diagnosed with medulloblastoma, a brain tumor at the age of 14 in 2006. He shared his fight against cancer in his book, *Carry Me*, which Carson hoped would offer encouragement and strength to other young cancer patients. He asked his family to make sure that researchers study the tumors in his brain, "because if those tumors can help some kid not die from cancer like I am, I'd like that, it's hard to have cancer." The Carson Leslie Foundation was established in his memory.

**"IN NAMING THIS ROOM FOR CARSON,
CPRIT HONORS ALL TEXANS AND THEIR FAMILIES
AND FRIENDS WHO HAVE BEEN AFFECTED BY CANCER."**

This photo of Carson with country and western recording artist and Poteet, Texas native George Strait hangs in The Carson Leslie Conference Room #TexasProud

CLF's mission statement affirms that it believes in synergy, collaboration, working together, and directing funds, and because of the unique relationship CLF has with CPRIT, its funding is tremendously leveraged.

"CPRIT has about $1.5 billion left to invest and with childhood cancer a CPRIT priority this could get really exciting!" Annette Leslie said in a news release.

CPRIT, in a statement, promises to "maintain the highest integrity and dedication to the mission of finding a cure for cancer. CPRIT's objective is to position Texas as a world-class leader in research and prevention through collaboration with a variety of entities, including public and private institutions of higher education, academic health institutions, universities, governmental and nongovernmental organizations, public and private companies, and others involved in the fight against cancer."

The Carson Leslie Awards for Pediatric Brain Cancers, a result of a unique relationship between CLF and CPRIT, have funded over $3.2 million in research for less toxic childhood brain cancer treatments. Recipients include:

• The University of Texas Southwestern Medical Center, for Genotype and Metabolic Phenotype in Pediatric Brain Cancer;

• Baylor College of Medicine, for Proton Beam Radiation Therapy vs. Conventional Beam Radiation Therapy Toxicities During and After Craniospinal Radiation Therapy in Children;

• Texas Tech University Health Science Center (using tumors from Carson), for Rational Redox-Driven Non-Toxic Therapeutic Strategies for Pediatric Brain Cancers.

The Carson Leslie Awards a $3,200,000 CPRIT/CLF collaborative investment!

CPRIT Grants	Investigator	Institution	City
Rational Redox-Driven Non-Toxic Therapeutic Strategies For Pediatric Brain Cancers (Carson Leslie Award)	Srivenugopal, Kalkunte	Texas Tech University Health Sciences Center	Lubbock
Proton Beam Radiation Therapy vs. Conventional Beam Radiation Therapy: Toxicities During & After Craniospinal Radiation Therapy in Children (Carson Leslie Award)	Ris, M Douglas	Baylor College of Medicine	Houston
Genotype and Metabolic Phenotype in Pediatric Brain Cancer (Carson Leslie Award)	Maher, Elizabeth A	University of Texas Southwestern Medical Center	Dallas

A February 2016 Report submitted to the CPRIT Oversight Committee by the CPRIT Advisory Committee on Childhood Cancer (ACCC) notes that the success of CPRIT research applications focused on childhood cancer has risen substantially, in large part due to focused RFA mechanisms that have resulted in the funding of more than 30 childhood and cancer research projects to date.

Specifically, the report says an increase has been noted in the number of grants devoted to childhood and adolescent cancers (from 4 to 13 percent); prevention and early detection (13 to 17 percent); and computational biology (2 to 4 percent).

The ACCC anticipates that these numbers will continue to increase with the release of targeted RFAs devoted to these priority areas, noting, "This impact is tremendous since the life years impacted by survivors of childhood cancer greatly exceeds that of adult cancer survivors. Further evidence of this success is measured by publications and new grant dollars."

Although that impact in this regard will take an additional three to five years to mature, the ACCC says even at this early juncture there have been more than 65 peer review publications, with numerous others in progress, that have come from these CPRIT-funded pediatric-focused research projects. These include publications in high-impact journals such as the Journal of Clinical Oncology, Blood, Nature Reviews, and Nature Communications. Additionally, CPRIT-funded investigators have been able to garner an additional $10 million in peer review funding to support their pediatric cancer research initiatives.

The report observes that CPRIT-funded research initiatives focused on pediatric cancer range from prevention strategies to survivorship. The majority of funded awards are Individual Investigator Research Awards, although there are also two funded Multi-Investigator Research Awards, including one on osteosarcoma and another on soft tissue sarcomas.

The report concludes: "The ACCC is grateful to CPRIT for its commitment to prioritizing and funding groundbreaking cancer research and prevention programs that are focused on childhood cancer. This commitment will have a profound impact for children with cancer and their families both locally and globally."

https://bionews-tx.com/news/2016/04/18/cprits-conference-room-carson-leslie/

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	NED HOLMES, NOMINATIONS SUBCOMMITTEE CHAIR
SUBJECT:	INTENTION TO RECOMMEND APPROVAL OF APPOINTMENTS TO THE SCIENTIFIC RESEARCH AND PREVENTION PROGRAMS COMMITTEE
DATE:	MAY 13, 2016

Summary and Recommendation:

The Chief Executive Officer has appointed 15 reviewers to CPRIT's Scientific Research and Prevention Programs Committee. Two appointments are to the product development research review panels, seven appointments are to the prevention panels, and six appointments are to academic research panels. CPRIT's statute requires the appointments be approved by the Oversight Committee. The Nominations Subcommittee discussed the appointments at its meeting on May 13, 2016, and recommends that the Oversight Committee vote to approve the appointments.

Discussion:

Scientific Research and Prevention Programs committee members (also referred to as "peer reviewers") are responsible for reviewing grant applications and recommending grant awards for meritorious projects addressing cancer prevention and research, including product development research. Peer reviewers perform an important role for the state; all CPRIT grant awards must be first recommended by a Scientific Research and Prevention Programs committee. Individuals appointed to serve as CPRIT's Scientific Research and Prevention Programs committee members are exceptionally qualified, highly respected, well-established members of the cancer research, product development research, and prevention communities.

Texas Health and Safety Code Section 102.151(a) directs the Chief Executive Officer to appoint members to the Scientific Research and Prevention Programs committees. The CEO's appointments are final once approved by a simple majority of the Oversight Committee. The Nominations Subcommittee charter assigns the subcommittee with the responsibility "to circulate to Oversight Committee members in advance of a public meeting written notification of the committee's intent to make the nomination, along with such information about the nominee as may be relevant."

The Nominations Subcommittee considered the pending appointments and recommends Oversight Committee approval. Biosketches for the appointees are attached.

Recommendations for Scientific Research Peer Review Panels

- Jennifer Grandis
- Ling Jong
- Nouri Neamati
- Michael Prados
- George Prendergast
- Brian Wolpin

Recommendations for Prevention Peer Review Panels

- Alice Ammerman
- Joan Bloom
- Richard Clayton
- Mindie Nguyen
- Jennifer Redmond Knight
- Jamie Studts
- Karen Williams

Recommendations for Product Development Peer Review Panels

- Paul Benny
- Rao P. Gullapalli

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. ***DO NOT EXCEED FIVE PAGES****.*

NAME: Grandis, Jennifer R.

eRA COMMONS USER NAME (credential, e.g., agency login): jgrandis

POSITION TITLE: Professor

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Swarthmore College, Swarthmore, Pennsylvania	BA	06/82	Biology
Swarthmore College, Swarthmore, Pennsylvania	BA	06/82	Art History
University of Pittsburgh School of Medicine, Pittsburgh, PA	MD	06/87	Magna Cum Laude

A. Personal Statement

I am Associate Vice Chancellor for Clinical and Translational Research and Professor of Otolaryngology-Head and Neck Surgery at the University of California, San Francisco (UCSF) where I also direct the Clinical and Translational Science Institute (CTSI). At UCSF, I am responsible for leading and shaping the strategic direction of the translational research enterprise including overseeing all aspects of clinical trials infrastructure and processes. In this role, I work coordinately with the Medical Center, the entire Executive Vice Chancellor and Provost (EVCP) organization, the four Schools and Graduate Division, and key Organized Research Units and Centers across the campus. My own research efforts are focused on elucidating and targeting key signaling pathways in head and neck cancer. I directed the head and neck cancer program at the University of Pittsburgh Cancer Institute from 1998-2014, where I was a Distinguished Professor. In this capacity, I facilitated collaborations between clinicians and investigators with an emphasis of developing a robust research infrastructure to support clinical and translational cancer studies. I served as PI of the NCI-supported specialized program of research excellence (SPORE) in Head and Neck Cancer at the University of Pittsburgh from 2002-2014 and now Co-PI in a MPI format (through 2020). I am also an American Cancer Society Clinical Research Professor (since 2008). I have held several leadership positions in the SPORE program including service on the SPORE Executive Committee (2007-2009) and Co-Chair of the Translational Science Meeting (2010-2011). I also serve on or chair the external scientific advisory boards for four other SPOREs. I am therefore qualified to serve on the external advisory board for the SPORE in Head and Neck Cancer from UCSD.

B. Positions and Honors

Positions and Employment

1987-1988 Surgical Intern, Surgery, University of Pittsburgh
1988-1993 Resident, Otolaryngology, University of Pittsburgh
1991-1992 Research Fellow, Medicine, University of Pittsburgh
1993-1998 Assistant Professor, Otolaryngology & Pharmacology (Secondary Appointment), University of Pittsburgh
1999-2004 Associate Professor, with tenure, University of Pittsburgh
1998-2015 Program Leader, Head & Neck Cancer Program, University of Pittsburgh Cancer Institute (UPCI)
2004-2015 Professor, Otolaryngology & Pharmacology (Secondary Appointment), University of Pittsburgh
2005-2015 Vice Chair for Research, Otolaryngology, University of Pittsburgh
2005-2015 UPMC Endowed Chair, Head & Neck Cancer Surgical Research, University of Pittsburgh
2010-2015 Assistant Vice Chancellor, Research Program Integration in the Health Sciences, University of Pittsburgh
2012-2015 Distinguished Professor, Otolaryngology, University of Pittsburgh
2015-present Associate Vice Chancellor, Clinical and Translational Research, University of California, San Francisco
2015-present Professor, Otolaryngology - Head & Neck Surgery, University of California, San Francisco

Other Experience and Professional Memberships

2000-present Ad hoc reviewer, NIH Study Sections
2001-2003 Member, NIH Metabolic Pathology (MEP) Study Section
2003-2006 Chair, NIH Tumor Cell Biology (TCB) Study Section
2008-2011 Member, NIH Tumor Cell Biology Study Section
2010-2013 Member, American Association of Cancer Research, Board of Directors
2012-2014 Member, NIH/NIDCR, Board of Scientific Counselors
2013-2015 Member, NIH Basic Mechanisms of Cancer Therapeutics (BMCT) Study Section
2014-2017 Chair, NIH/NIDCR, Board of Scientific Counselors

Honors

1986 Alpha Omega Alpha (AOA), University of Pittsburgh
1987 M. D. Magna Cum Laude, University of Pittsburgh School of Medicine
2002 Elected Member, American Society for Clinical Investigation
2003 Scientific Leadership Award, University of Pittsburgh Cancer Institute
2005 Endowed Chair in Head and Neck Surgical Research, University of Pittsburgh Medical Center
2008 Clinical Research Professorship, American Cancer Society
2009 Chancellor's Distinguished Research Award, University of Pittsburgh
2010 Elected Member, Association of American Physicians
2011 Provost's Award for Excellence in Mentoring, University of Pittsburgh
2012 Distinguished Professor of Otolaryngology, University of Pittsburgh
2012 Alton Oschner Award Relating Smoking and Disease, Oschner Research
2012 NIH Pittman Lecturer (Wednesday Afternoon Lecture Series/WALS), NIH
2012 Elected Member, Institute of Medicine (IOM) of The National Academies
2014 William E. Brown Outstanding MSTP Mentor Award, Medical Scientist Training Program, University of Pittsburgh and Carnegie Mellon University
2015 Peggy Wheelock Award for Excellence in Research, Mentoring, and Promotion of Women in Science, University of Nebraska Medical Center

C. Contribution to Science

1. My group was among the first to demonstrate that the epidermal growth factor receptor (EGFR) is unregulated and overexpressed in head and neck cancers. EGFR expression levels in the head and neck tumor were found to be prognostic and targeting EGFR in preclinical models was associated with antitumor

effects. These studies were seminal to the development of anti-EGFR therapeutics for the treatment of head and neck cancer, culminating in the FDA approval of the EGFR targeted monoclonal antibody cetuximab for this disease in 2006. Our group also developed an antisense gene therapy approach to inhibiting EGFR which was patented, demonstrated no toxicity and efficacy in phase I testing and recently completed phase II testing in combination with cetuximab and radiation.

a. **Grandis JR**, Zeng Q, Tweardy DJ. Retinoic acid normalized the increased gene transcription rate of TGF-alpha and EGFR in head and neck cancer cell lines. Nature Medicine. 1996 Feb; 2(2): 237-40. PMID: 8574972.
b. **Rubin Grandis J**, Melhem MF, Gooding WE, Day R Holst VA, Wagener MM, Drenning SD, Tweardy DJ. Levels of TGF-alpha and EGFR protein in head and neck squamous cell carcinoma and patient survival. Journal of the National Cancer Institute. 1998 Jun 3; 90(11): 824-32. PMID: 9625170.
c. He Y, Zeng Q, Drenning SD, Melhem MF, Tweardy DJ, Huang L, **Grandis JR**. Inhibition of human squamous cell carcinoma growth in vivo by EGFR antisense RNA transcribed from the U6 promoter. Journal of the National Cancer Institute. 1998 Jul 15; 90(14): 1080-7. PMID: 9672256.
d. Lai SY, Koppikar P, Thomas SM, Childs E, Egloff AM, Seethala R, Branstetter BF, Gooding WE, Muthukrishnan A, Mountz JM, Lui VWY, Shin DM, Agarwala SS, Johnson R, Couture LA, Myers EN, Johnson JT, Mills G, Argiris A, **Grandis JR**. Intratumoral Epidermal Growth Factor Receptor antisense DNA therapy in head and neck cancer: first human application and potential antitumor mechanisms. Journal of Clinical Oncology. 2009 Mar 10; 27(8):1235-42. Epub 2009 Feb 9. PMC2667824.

2. We identified STAT3 as an oncogenic therapeutic target in head and neck cancer and demonstrated its role in treatment resistance. My laboratory developed a transcription factor decoy oligonucleotide to target STAT3-mediated gene transcription. We obtained an investigator initiated IND and designed and completed a phase 0 clinical trial demonstrating the pharmacodynamics effects of this approach. We further modified the STAT3 decoy to enable systemic delivery, obtained a patent and a phase I trial is pending.
   a. **Grandis JR**, Drenning SD, Chakraborty A, Zhou MY, Zeng Q, Pitt AS, Tweardy DJ. Requirement of Stat3 but not Stat1 activation for epidermal growth factor receptor-mediated cell growth in vitro. Journal of Clinical Investigation. 1998 Oct; 102(7): 1385-92. PMID: 9769331.
   b. **Grandis JR**, Drenning SD, Zeng Q, Watkins SF, Melhem MF, Endo S, Johnson DE, Huang L, Kim JD. Constitutive activation of Stat3 signaling abrogates apoptosis in squamous cell carcinogenesis in vivo. Procedings of the National Academy of Sciences USA. 2000 Apr 11; 97(8):4227-32. PMID: 10760290.
   c. Leong, PL, Andrews GA, Johnson DE, Dyer KF, Xi S, Mai JC, Robbins PD, Gadiparthi S, Burke NA, Watkins SF, **Grandis JR**. Targeted inhibition of Stat3 with a decoy oligonucleotide abrogates head and neck cancer cell growth. Proc Natl Acad Sci U S A. 2003 Apr 1;100(7):4138-43. Epub 2003 Mar 14. PMC153061
   d. Sen M, Thomas SM, Kim, SW, Yeh JI, Ferris RL, Johnson JT, Duvvuri U, Lee JA, Sahu N, Joyce S, Freilino ML, Shi H, Li C, Ly D, Rapireddy S, Etter JP, Li PK, Wang L, Chiosea S, Seethala RR, Gooding WE, Chen X, Kaminski N, Pandit K, Johnson DE, **Grandis JR**. First-in-human trial of a STAT3 decoy oligonucleotide in head and neck tumors: implications for cancer therapy. Cancer Discovery. 2012 Aug; 2(8): 694-705. Epub 2012 Jun 20. PMC3668699.

3. We have been at the forefront of genomic medicine in head and neck cancer leading several efforts to elucidate the genomic underpinnings of head and neck squamous cell carcinoma. I co-chaired The Cancer Genome Atlas (TCGA) working group to characterize the genetic and epigenetic profile of human HNSCC tumors.
   a. Stransky N, Egloff AM, Tward A, Kostic A, Cibulskis K, Sivachenko A, Kryukov G, Lawrence M, Sougnez C, McKenna A, Ramos AH, Stojanov P, Carter SL, Voet D, Cortes M, Auclair D, Saksena G, Guiducci C, Onofrio R, Parkin M, Romkes M, Weissfeld J, Seethala RR, Wang L, Winckler W, Ardlie K, Gabriel SB, Myerson M, Lander ES, Getz G, Golub TR, Garraway LA, **Grandis JR**. The mutational landscape of head and neck squamous cell carcinoma. Science. 2011 Aug 26; 333(6046):1157-60. Epub 2011 Jul 28. PMC3415217.
   b. Gross AM, Orosco RK, Shen JP, Egloff AM, Carter H, Hofree M, Choueiri M, Coffey CS, Lippman SM, Hayes DN, Cohen EE, **Grandis JR**, Nguyen QT, Ideker T. Multi-tiered genomic analysis of head and neck cancer ties TP53 mutation to 3p loss. Nat Genet. 2014 Aug 3. [Epub ahead of print]. PMC4146706

c. Hammerman PS, Hayes DN, **Grandis JR**. Therapeutic insights from genomic studies of head and neck squamous cell carcinomas. Cancer Discov. 2015 Mar; 5(3):239-44. PMID: 25643909. PMCID: PMC4355279
d. Hayes, N, Sheth M, El-Nagger AJ, **Grandis JR**, Zenklusen JC. Comprehensive genomic characterization of head and neck squamous cell carcinomas. Nature, 2015 January 29; 517(7536):576-82.
e. Hedberg ML, Goh G, Chiosea SI, Bauman JE, Freilino ML, Zeng Y, Wang L, Diergaarde BB, Gooding WE, Lui VWY, Herbst RS, Lifton RP and **Grandis, JR.** The Genetic Landscape of Metastasis and Recurrence in HNSCC. *The Journal of Clinical Investigation.* 2015 Nov 30. pii: 82066. doi: 10.1172/JCI82066. [Epub ahead of print] PMID: 26619122.

4. We developed preclinical models, including patient-derived xenografts (PDXs), to determine gain of function genetic alterations in head and neck tumors, with the ultimate goal of identifying precision medicine approaches for this cancer.
   a. Lui VW, Hedberg ML, Li H, Vangara B, Pendleton K, Zeng Y, Lu Y, Zhang Q, Du Y, Gilbert B, Freilino M, Sauerwein S, Peyser N, Xiao D, Diergaarde B, Wang L, Chiosea S, Seethala RR, Johnson JT, Kim S, Duvvuri U, Ferris RL, Romkes M, Nukui T, Ng P, Garraway L, Hammerman P, Mills GB, **Grandis JR.** Frequent mutation of the PI3K pathway in head and neck cancer defines predictive biomarkers. Cancer Discovery. 2013 Jul;3(7):761-9. Epub 2013 Apr 26. PMC3710532.
   b. Lui V, Peyser ND, Ng PK, Hritz J, Zeng Y, Lu Y, Hua L, Wang L, Gilbert BR, General IJ, Bahar I, Ju Z, Wang Z, Pendleton KP, Xiao X, Du Y, Vries JK, Hammerman PS, Garraway LA, Mills GB, Johnson DE, **Grandis JR.** Frequent mutation of receptor protein tyrosine phosphatases provides a mechanism for STAT3 hyperactivation in head and neck cancer. Proc Natl Acad Sci U S A. 2014 Jan 21; 111(3):1114-19. PMC3903220.
   c. Li H, Wawrose JS, Gooding WE, Garraway LA, Lui VWY, Peyser ND, **Grandis JR.** Genomic analysis of head and neck squamous cell carcinoma cell lines and human tumors: a rational approach to preclinical model selection. Molec Cancer Res. 2014 Apr;12(4):571-82. PMC3989421.
   d. Li H, Wheeler S2, Park YS3, Ju Z4, Thomas SM5, Fichera M6, Egloff AM7, Lui VW8, Duvvuri U9, Bauman JE10, Mills GB11, **Grandis JR**12 Proteomic Characterization of Head and Neck Cancer Patient-Derived Xenografts*. Mol. Cancer Res* Published Online First December 18, 2015; pii: molcanres. 0354.2015. [Epub ahead of print] doi: 10.1158/1541-7786.MCR-15-0354. PMID: 26685214.

5. Our group pioneered the use of window of opportunity studies in HNSCC to determine the pharmacodynamic effects of molecular targeting agents coupled with surrogate measures of clinical response. This study validated K167 labeling in the post treatment tumor (compared with pre-treatment sample) as an indicator of drug activity.
   a. Gross ND, Bauman JE, Gooding WE, Denq W, Thomas SM, Wang L, Chiosea S, Hood BL, Flint MS, Sun M, Conrads TP, Ferris RL, Johnson JT, Kim S, Argiris A, Wirth L, Nikiforova MN, Siegfried JM, **Grandis JR**. Erlotinib, erlotinib-sulindac vs. placebo: a randomized, double-blind, placebo-controlled window trial in operable head and neck cancer. Clinical Cancer Research. Epub 2014 Apr 11. PMC4104657.

Complete List of Published Work in MyBibliography:
http://www.ncbi.nlm.nih.gov/sites/myncbi/jennifer.grandis.1/bibliograpahy/40477950/public/?sort=date&direction=ascending

D. Research Support

On-going Research Support

UL1TR000004-09 Grandis (PI) 09/30/2011-06/30/2016
NIH-NCATS UCSF Clinical and Translational Science Institute
The UCSF Clinical and Translational Institute (CTSI) at the University of California, San Francisco (UCSF) was established in 2006 to accelerate the pace of research that improves the health of the public. The overall mission of CTSI is to improve and transform clinical and translational research infrastructure and training at UCSF and partner institutions.

Role: PI

The V Foundation for Cancer Research Bauman (PI) 11/01/2014-10/31/2017
2015 V Translational Research Agreement
Genetic Alterations of PIK3CA Identify Actionable Targets for HPV-Associated Head and Neck Cancer. We will test the idea that PIK3CA pathway activation, both directly by HPV oncoproteins, and indirectly through accumulated genetic changes in PIK3CA, drive benign HPV infections to transform inter cancers.
Role: Co-Investigator

P50 CA097190 Ferris/Grandis (PI) 02/12/2015-06/30/2020
NIH/NCI Specialized Program of Research Excellence (SPORE) in Head and Neck Cancer
The goal of this program is to improve the prevention, detection, and treatment of head and neck cancer through translational research.
Role: PI/MPI

R01 CA077308 Grandis (PI) 08/01/1998-05/31/2019
NIH/NCI STAT-Mediated TGF-alpha/EGFR Signaling in SCCHN
The major goal of this grant is to elucidate the role of STAT-mediated EGFR signaling in head and neck cancer.
Role: PI

R01 CA098372 Grandis (PI) 07/01/2014-05/31/2018
NIH/NCI GRPR in SCCHN: Integration with EGFR
The major goal of this grant is to elucidate interactions between GRPR and EGFR in SCCHN.
Role: PI

R01 DE023685 Grandis (PI) 05/01/2014-02/28/2019
NIH/NIDCR PI3KPathway Mutations in Head and Neck Cancer
The major goal of this proposal is to determine the predictive role of Pi3K alterations in head and neck cancer.
Role: PI

R01 EB016516 Villanueva (PI) 07/01/0012-05/31/0016
NIH/NIBIB Ultrasound-activated Microbubbles for Targeted siRNA Delivery to Tumor
The major goal will establish general principles that can be extended to US-MB siRNA platforms for image-guided Targeted gene silencing in other diseases for which specific gene silencing represents a therapeutic approach.
Role: Co-I

F30 CA180235 Hedberg (PI) 06/01/2014-10/31/2017
NIH/NCI Phosphoinositol-3-Kinase Signaling and PIK3CA:Critical Mitogenic Drivers in Head and Neck Cancer
Role: Mentor

Completed Research Support

R21 CA167373 Villanueva (PI) 08/10/2012-07/31/2015
NIH/NCI
Targeted Theranostic Microbubble Vectors for Transcription Factor Decoy Delivery
The major goal is to train Otolaryngologists for careers that combine cancer research with clinical practice.
Role: Co-I

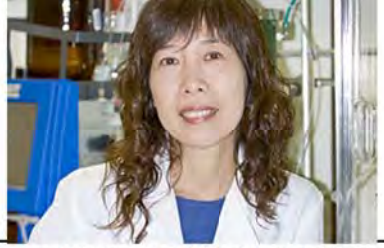
F31 DE024007 09/01/2013-06/30/2015
NIH/NIDCR
Genomic alteration of PTPRT in OSCC: Implications for STAT3 pathway targeting
Role: Mentor

T32 CA060397 09/01/2005-08/31/2014
NIH/NCI
Postdoctoral Research Training in Head and Neck Oncology (PI until 03/01/14)

Role: PI

K07 CA137140 09/04/2009-08/31/2014
NIH/NCI
Genomic and Proteomic Biomarkers for Head and Neck Cancer Risk & Prognosis
Role: Mentor

2T32DC000066 07/01/2003-06/30/2018
NIH/NIDCD
Research Training in Otolaryngology (transferred 1/1/15)
Role: PI



BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Jong, Ling	Senior Program Director, Medicinal Chemistry
eRA COMMONS USER NAME	Biosciences Division, SRI International
LINGJONG	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
National Chung-Hsing University, Taiwan	B.S.	1983	Chemistry
Florida State University, Tallahassee	Ph.D.	1991	Organic chemistry
SRI International, Menlo Park, CA	Postdoc.	1992–1993	Medicinal chemistry

A. SUMMARY STATEMENT

During 20+ years of work in drug discovery and development at SRI, I was able to integrate biology and medicinal chemistry into drug discovery research, and have successfully delivered several new chemical entities (NCEs) into preclinical and clinical development to treat cancer. These drugs include Targretin® (Bexarotene), now on the market for treatment of cutaneous T-cell lymphoma, SR16234 (TSA-108), a selective estrogen receptor modulator (SERM) that has reached Phase II clinical trials for the treatment of tamoxifen-resistant breast cancer, and SR13668, an AKT inhibitor, completed Phase 0 clinical trial.

I served as Principal Investigator on multiple drug discovery and development projects for cancer, infectious disease and neurodegenerative diseases. I regularly interact with multidisciplinary research teams and oversee IND-enabling studies. My overall responsibilities include initiating and leading drug discovery efforts, building cross-functional teams to advance drug candidates into IND-enabling studies and clinical development.

B. POSITIONS AND HONORS

Positions and Employment

1984–1985 Research Assistant, under the direction of Professor R. A. Holton, Department of Chemistry, Virginia Polytechnic Institute and State University, Blacksburg, VA
1985–1991 Research Assistant, under the direction of Professor R. A. Holton, Department of Chemistry, Florida State University, Tallahassee, FL
1992–1993 Postdoctoral Fellow, Bio-Organic Chemistry Laboratory, SRI International, Menlo Park, CA
1993–2001 Medicinal Chemist, Pharmaceutical Discovery, SRI International, Menlo Park, CA
2001–2003 Senior Medicinal Chemist, Pharmaceutical Discovery, SRI International, Menlo Park, CA
2004–2008 Program Director, Medicinal Chemistry, Center for Translational Drug Discovery and Development, Biosciences Division, SRI International
2008–present Senior Program Director, Medicinal Chemistry, Biosciences Division, SRI International

Professional Service

Scientific reviewer, DoD, Breast Cancer Research Program, Experimental Therapeutics section (2007–present); Susan G. Komen for the Cure Foundation, Experimental/target Therapeutics section (2008–present)

Honors

- Outstanding Achievement Awards, SRI International (1995, 2002)
- Outstanding CBCRP New Investigator Awards
- First Place for Innovation category, Cornelius L. Hopper Award at the March 2002 CABCRP Program Annual Meeting
- Honorable mentions for "Best Presentation category, Cornelius L. Hopper Award at the California Breast Cancer Research Program Annual Meeting in both 2002 and 2003
- Front page story in the Silicon Valley *San Jose Business Journal* on October 1, 2004
- Most-Accessed Articles published in Journal of Medicinal Chemistry (2007)
- Outstanding Funded Research, Idea Award, CDMRP/Prostate Cancer Research Program (2008)
- Golden Nugget Awards, SRI International (2005, 2007, 2009, 2011, 2012, 2013)

Significant Scientific Achievements

Design of a novel class of retinoid X receptor selective ligands for treatment of lymphoma. The patents listed below were licensed to Ligand Pharmaceuticals/, and the compound was developed as the drug Targretin® (Bexarotene) now on the market for treatment of cutaneous T-cell lymphoma (CTCL).

- Dawson MI, Cameron JF, Hobbs PD, **Jong L**, Pfahl M, Zhang X, Lehmann JM. Bridged bicyclic aromatic compounds and their use in modulating gene expression of retinoid receptors. U.S. Patent 5,466,861, November 15, 1995.

Design of a novel steroidal-selective estrogen receptor modulator (SERM) for treatment of drug-resistant breast cancer. The patent listed below was licensed to Taiho Pharmaceuticals Co., Ltd., and developed jointly by Taiho and SRI. SR16234 (TSA-108) is in Phase II clinical trials as a potential treatment for tamoxifen-resistant breast cancer.

- Tanabe M, Peters RH, Chao W-R, **Jong L**. Anti-estrogenic steroids, and associated pharmaceutical compositions and methods of use. U.S. Patent 6,054,446, April 25, 2000.

Design of a novel class of retinoids with selective anti-AP-1 activity for cancer therapy. A patent application for this compound was filed. The class of compounds is described in the *Nature* publications, to which Dr. Jong was one of the major contributors.

- M. Pfahl, M. O. Lee, M. I. Dawson, P. D. Hobbs, A. Fanjul, **L. Jong**, G. Graupner, and X. P. Lu. Novel compounds useful in modulating gene expression of retinoid responsive genes and/or having anti-AP-1 activity. WO9533745, December, 14, 1995.

Design of a novel class of apoptosis inducers for leukemia. This invention provides pharmaceutical compositions and methods for treating mammals with leukemia or other forms of cancer or for treating disease conditions caused by apoptosis of cells.

- Hobbs P, **Jong L**, Leid M, Dawson MI, Zhang X-K, Fontana JA. Induction of apoptosis in cancer cells. WO03048101, June 12, 2003.

Design and development of novel dietary indole analogs for breast cancer prevention and treatment. Dr. Jong's research discovery won the First Place for Innovation category at the March 2002 CABCRP Program Annual Meeting. http://www.cbcrp.org/publications/newsletters/2002/CBCRP_fall02_newsl.pdf

Dr. Jong's success in drug discovery and development made her the front page story in the Silicon Valley *San Jose Business Journal* on Oct. 1, 2004. http://www.bizjournals.com/sanjose/stories/2004/10/04/story4.html

- **Jong L**, Chao W-R. Analogs of indole-3-carbinol metabolites as chemotherapeutic and chemopreventive agents. U.S. Patent 6,800,655, October 5, 2004.
- **Jong L**, Chao W-R. Analogs of indole-3-carbinol metabolites as chemotherapeutic and chemopreventive agents. U.S. Patent 7,429,610, September 30, 2008.

Design and development of novel src/surviving inhibitors for prostate cancer prevention and therapy. Dr. Jong was awarded a Department of Defense "Laboratory-Clinical Transition" grant to advance SRI's novel anticancer agents for prostate cancer treatment. http://www.sri.com/news/releases/101309.html

- **Jong L**, Chao W-R. Analogs of indole-3-carbinol metabolites as chemotherapeutic and chemopreventive agents. U.S. Patent 7,078,427, July 18, 2006.

Design and Development of novel Broad-Spectrum Agents for Prophylaxis and Treatment Against Bacterial Threats. On July 31, 2008, Dr. Jong was awarded an $8.3 million contract to develop broad-spectrum antibiotics for the Defense Threat Reduction Agency within the U.S. Department of Defense.

- **Jong L**, Jiang F, Li G, Mortelmans K. Analogs of indole-3-carbinol and their use as agents against infection, US application number 12/561656, September 17, 2009.

Design and Development of Novel lipoxygenase inhibitors to Treat Alzheimer's Disease. Design and develop dual lipoxygenase inhibitors that can cross the blood-brain barrier for AD treatment.

- **Jong L**. Lipoxygenase inhibitors, WO/2012/135133, April 10, 2012.

Design and Development of HGK kinase inhibitors to Treat Metastatic Cancer. Design and develop highly selective Type-II MAP4K4 (HGK) inhibitors for cancer *treatment.*

- **Jong L**, Chang C. and Park J. US Patent application Number 61/88120, entitled "HGK (MAP4K4) INHIBITORS ", filed Sept 25, 2013.

C. SELECTED PEER-REVIEWED PUBLICATIONS

Most relevant to the current application

1. Lehmann JM, **Jong L**, Fanjul A, Cameron JF, Lu XP, Haefner P, Dawson MI, Pfahl M. Retinoids selective for retinoid X receptor response pathways. Science 1992; 258:1944-1946.
2. **Jong L**, Lehmann JM, Hobbs PD, Harlev E, Huffman JC, Pfahl M, Dawson MI. Conformational effects on retinoid receptor selectivity. 1. Effect of 9-double bond geometry on retinoid X receptor selectivity. J Med Chem 1993; 36:2605-2613.
3. Fanjul A, Dawson MI, Hobbs PD, **Jong L**, Cameron JF, Harlev E, Graupner G, Pfahl M. A novel class of retinoids with selective anti-AP-1 activity exhibits anti-proliferative activity. Nature 1994; 372:107.
4. **Jong L**, Zaveri N, Toll LR. The design and synthesis of a novel quinolizidine template for the potent opioid and opioid receptor-like (ORL1, NOP) receptor ligands. Bioorg Med Chem Lett 2004;14:181-185.
5. Chao WR, Yean D, Amin K, Green C, **Jong L.** Computer-aided rational drug design: a novel agent (SR13668) designed to mimic the unique anticancer mechanisms of dietary indole-3-carbinol to block Akt signaling. J Med Chem 2007; 50: 3412-3415.

Additional recent publications of importance to the field (in chronological order)

6. Li Y, Dawson MI, Agadir A, Lee MO, **Jong L**, Hobbs PD, and Zhang X. Regulation of RAR beta expression by RAR- and RXR-selective retinoids in human lung cancer cell lines: Effect on growth inhibition and apoptosis induction. Int J Cancer 1998; 75: 88-95.
7. Dawson MI, Hobbs PD, **Jong L**, Xiao D, Chao WR, Pan C, and Zhang XK. sp2-Bridged diaryl retinoids: Effects of bridge-region substitution on retinoid X receptor (RXR) selectivity. Bioorg Med Chem Lett 2000; 10:1307-1310.
8. Dawson MI, **Jong L**, Hobbs PD, Xiao D, Feng KC, Chao WR, Pan C, Fontana JA, and Zhang XK. 4-[3-(5,6,7,8-Tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)phenyl]benzoic acid and heterocyclic-bridged analogues are novel retinoic acid receptor subtype and retinoid X receptor alpha agonists. Bioorg Med Chem Lett 2000; 10:1311-1313.
9. Dawson MI, Zhang X, Hobbs PD, and **Jong L**, Synthetic retinoids and their usefulness in biology and medicine. In *Vitamin A and Retinoids: An Update of Biological Aspects and Clinical Applications*, M.A. Livrea (Ed.), Birkhauser Verlag, Basel, Switzerland, 2000, pp. 161-196.
10. He H, Cho H-T, Li W, Kawakita T, **Jong L** and Tseng SC. Signaling transduction pathways required for ex vivo expansion of human limbal explants on intact amniotic membrane. Invest Ophthalmol Vis Sci. 2006; 47:151-157.
11. Frank GD, **Jong L**, Collins N, and Spack EG. Nonprofit model for drug discovery and development. Drug Develop Res 2007; 68:186-196.
12. Kapetanovic IM, Muzzio M, Hu SC, Crowell JA, Rajewski RA, Haslam JL, **Jong L**, McCormick DL. Pharmacokinetics and enhanced bioavailability of candidate cancer preventative agent, SR13668 in dogs and monkeys. Cancer Chemother Pharmacol 2010; 65(6):1109-16.
13. Green CE, Swezey R, Bakke J, Shinn W, Furimsky A, Bejugam N, Shankar GN, **Jong**, L and Kapetanovic IM. Improved oral bioavailability in rats of SR13668, a novel anti-cancer agent. Cancer Chemother Pharmacol, 2011;65(5): 995-1006.
14. Chao WR, Amin K, Shi Y, Hobbs P, Tanabe M, Tanga M, **Jong L**, Collins N, Peters R, Laderoute K, Dinh D, Yean D, Hou C, Sato B, Alt C, Sambucetti L. SR16388: a steroidal antiangiogenic agent with potent inhibitory effect on tumor growth in vivo. Angiogenesis 2011;14(1):1-16.
15. Green CE, Swezey R, Bakke J, Shinn W, Furimsky A, Bejugam N, Shankar GN, **Jong L**, Kapetanovic IM. Improved oral bioavailability in rats of SR13668, a novel anti-cancer agent. Cancer Chemother Pharmacol 2011; 67(5): 995-1006.
16. Reid JM, Walden CA, Qin R, Ziegler KL, Haslam JL, Rajewski RA, Warndahl R, Fitting CL, Boring D, Szabo E, Crowell J, Perloff M, **Jong L**, Bauer BA, Mandrekar SJ, Ames MM, Limburg PJ. Phase 0 clinical chemoprevention trial of the Akt inhibitor SR13668. Cancer Prev Res (Phila) 2011; 4(3):347-53.

D. RESEARCH SUPPORT

SRI Strategic Business Thrusts funding Jong (PI) 01/10/11–12/31/13
Develop in vitro cell culture models to evaluate lipoxygenase inhibitors for Alzheimer's disease.
The major goals are to establish and validate the neuronal cell-based assays as a screening platform for identifying compounds that inhibit Aβ formation.
Role: Principal Investigator

PC081641 DoD/PCRP Jong (PI) 09/09–09/13
Advancing Novel Dietary Indole Analogs into Preclinical Studies: Managing Prostate Cancer with Quality-of-Life Considerations
The goal of this study is to accelerate preclinical development of SRI novel MAP4K4 inhibitors for prostate cancer treatment and prevention.
Role: Principal Investigator

RAPID National Cancer Institute Jong (PI) 02/03–Phase I clinical trial
SR13668, A Novel Dietary Indole Analog for Cancer Prevention
The goal of this study is to expedite movement of novel molecules and concepts from the laboratory to the clinic for clinical trials of efficacy. RAPID supports Phase 0 clinical studies of SR13668.
Role: Principal Investigator

1R21NS062168-01 Kilduff (PI) 09/08–08/11
Hypocretin Agonists as Treatment for Narcolepsy and Wakefulness Promotion
The goal of this study is to design and synthesize hypocretin agonists for treatment of narcolepsy.
Role: Co-Investigator

HDTRA1-08-C-0050 DoD/DTRA/TMTI Jong (PI) 04/08–07/11
Broad-Spectrum Agents for Prophylaxis and Treatment Against Bacterial Threats
The goal of this study is to rapidly develop, through IND, a novel agent with proven antibacterial activity for prophylaxis and therapy.
Role: Principal Investigator

NF050021 DOD/Neurofibromatosis Research Program (NFRP) 11/05–11/08
Identification of Small Molecule Inhibitors of Pak for the Treatment of Neurofibromatosis Type 2
The goal of this program was to design and synthesize Pak2 inhibitors for the treatment of neurofibromatosis Type 2.
Role: Co-PI

PC020470 DoD/PCRP Jong (PI) 4/03–4/07
Novel Dietary Indole Analogs for Prostate Cancer Treatment: Managing Prostate Cancer with Quality of Life Considerations
The goals of this project included rational lead-based drug design, molecular modeling, quantitative structure-activity analysis, and *in vitro* and *in vivo* preclinical development of novel dietary indole analogs for prostate cancer treatment.
Role: Principal Investigator

9WB-0110 CBCRP Jong (PI) 7/03–12/06
Dietary Indole Analogs Inhibit Breast Cancer Cell Invasion
The major goal of this project was preclinical development of SR13668 as a long-term adjuvant therapeutic to prevent cancer recurrence and metastatic spread.
Role: Principal Investigator

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Nouri Neamati, Ph.D.

POSITION TITLE: John G. Searle Professor of Medicinal Chemistry

eRA COMMONS USER NAME (credential, e.g., agency login): neamati

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
University of Houston, Houston, TX	M.S.	1990	Medicinal Chemistry
University of Texas, GSBS-MDACC, Houston	Ph.D.	1995	Biomedical Sciences
National Institutes of Health, NCI	Postdoc	1999	Molecular Pharmacology

A. Personal Statement

Areas of primary interest to my laboratory include 1) synthetic medicinal chemistry, structure- and ligand-based drug design, 2) cellular and molecular pharmacology, and 3) preclinical drug development. Specifically, we are interested in performing in-depth preclinical pharmacology of a series of promising small-molecule compounds that we have recently discovered for the treatment of various cancers. I have extensive expertise in the proposed areas of research and have demonstrated leadership in the field of drug discovery and molecular pharmacology. I was trained at the MD Anderson Cancer Center (MDACC) in the general area of small- molecule synthetic medicinal chemistry and molecular pharmacology. While at MDACC I designed and synthesized a series of novel anthracyclines that showed remarkable activity in MDR1 overexpressing cells. Subsequently, I performed extensive cellular and molecular pharmacology studies to better understand the mechanisms of these compounds and carried out mouse xenograft studies to determine their *in vivo* efficacy. After my arrival at the Laboratory of Molecular Pharmacology, at the National Cancer Institute I expanded my research to include design and discovery of novel HIV-1 integrase inhibitors. At the University of Southern California and the University of Michigan I have built a robust chemoinformatic platform that has allowed us to design a series of highly promising drugs for the treatment of several cancers. An in-house library of 40,000 small-molecules representing 5 million compounds supports our large structural database. We have in place several cell and animal models of various cancers that are effective in elucidating the in vivo efficacy of our compounds. As a result, my laboratory has several compounds in various stages of development. I have developed extensive collaborations with other scientists and clinicians at the University of Michigan and other institutions to complement our expertise and expedite the clinical translation of our research. In my current position as a John G. Searle Professor of Medicinal Chemistry, I am supervising 12 predoctoral and postdoctoral fellows and managing all issues related to collaborations, publications, grants, research protections, budget, animal protocols, etc. I have served in numerous study sections and was a member of the NIH Drug Discovery and Molecular Pharmacology (DMP) Study Section. In summary, I have demonstrated a record of successful and productive research projects in the area of small-molecule drug design and discovery and preclinical pharmacology. With over 20 years of expertise in drug development I have the necessary skills to significantly contribute to this project.

My new laboratories (synthetic, computational, and pharmacology) at the University of Michigan are a part of the Translational Oncology Program located in the former Pfizer facility. This new program has allowed me to efficiently collaborate with numerous faculty members from the Cancer Center. A major emphasis of my laboratory has been the discovery of breakthrough therapeutics for various cancers. My computational and synthetic chemistry laboratories are equipped with all modern equipment and will be used for this project.

B. Positions and Honors

Positions and Employment

1986-1995	Senior Research Assistant, M.D. Anderson Cancer Center, Houston, TX.
1995-1999	Postdoctoral Fellow, National Cancer Institute, NIH, Bethesda, MD.
1999-2000	Research Fellow, National Cancer Institute, NIH, Bethesda, MD.
2000-2006	Assistant Professor, Department of Pharmaceutical Sciences, School of Pharmacy, University of Southern California, Los Angeles, CA.
2000-2013	Member, USC Norris Comprehensive Cancer Center
2007-2011	Associate Professor (tenured), Department of Pharmaceutical Sciences, School of Pharmacy, University of Southern California, Los Angeles, CA.
2011-2013	Professor (tenured), Department of Pharmaceutical Sciences, School of Pharmacy, University of Southern California, Los Angeles, CA.
2013-present	John G. Searle Professor of Medicinal Chemistry, College of Pharmacy, University of Michigan Ann Arbor, MI.
2013-present	Member, UM Comprehensive Cancer Center

Other Experience and Professional Memberships

2008-2012	Editor-in-Chief, *Current Molecular Pharmacology*
2001-	Associate Editor, *Current Cancer Drug Targets* (Impact Factor 4.7)
2001-2005	Editorial Advisory Board, *Current Topics in Medicinal Chemistry* (Impact Factor 4.1)
2001-	Editorial Advisory Board, *Expert Opinion on Investigational Drugs* (Impact Factor 5.2)
2006-	Editorial Advisory Board, *Expert Opinion on Drug Discovery* (Impact Factor 2.3)
2004-	Editorial Advisory Board, *Therapy*
2010-2012	Editorial Advisory Board, *Hormones & Cancer*
2012-	Editorial Advisory Board, *Journal of Medicinal Chemistry* (Impact Factor 5.6)
2000-	Associate Member American Association for Cancer Research and American Chemical Society

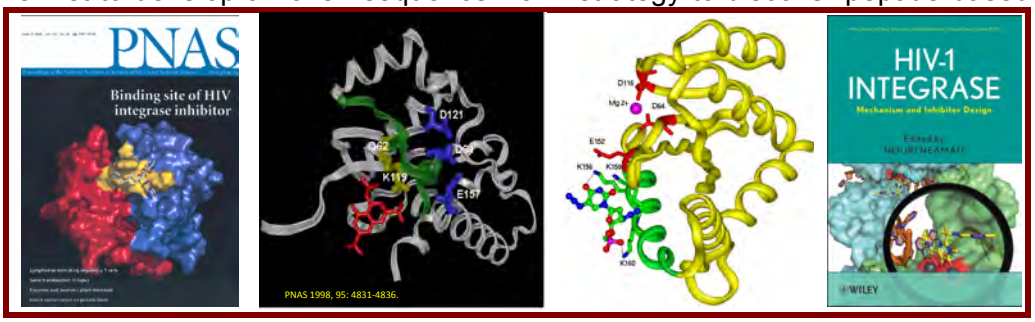
Honors and Awards

1995-1998	Intramural Research Training Award, National Cancer Institute, NIH
1998-1999	Cancer Research Training Award, National Cancer Institute, NIH
1998	Scientific Accomplishments as a Mentor, Howard Hughes Medical Institute & NIH
1999	Scientific Accomplishments as a Mentor, Science & Technology Internship Program
2000	Federal Technology Transfer Award, NIH
2001	STOP CANCER Award
2002	Drug Discovery and Development Award, GlaxoSmithKline
2005	DOD BCRP Concept Award, Department of Defense CDMRP
2006	LUNGevity Discovery Award, American Lung Association
2006	The Littlefield-AACR Award in Metastatic Colon Cancer Research, AACR
2010	DOD LCRP Concept Award, Department of Defense CDMRP
2010	DOD BCRP Idea Award, Department of Defense CDMRP
2012	DOD LCRP Concept Award, Department of Defense CDMRP
2014	DOD OCRP Pilot Award, Department of Defense CDMRP
Reviewer	NIAID, MIP Study Section, Special Emphasis Panel
Reviewer	NIAID and NCI, NIH Inter-Institute Program for the Development of AIDS-Related Therapeutics
Reviewer	SBIR Topic on Chemical Optimization and Structure Activity Relationships
Chair	SBIR Topic on Chemical Optimization and Structure Activity Relationships
Reviewer	NIH ADDT, ZCA1 GRB-P O1 and DMP Study Sections
Reviewer	DOD Breast Cancer Program, AACR, and other private foundations
2007-2013	Member; NIH Drug Discovery and Molecular Pharmacology Study Section
2015	Ad hoc reviewer, NCI Omnibus R21/R03 Review Meeting
2015	Ad hoc reviewer, NCI Exploratory/Developmental Research Grant Program (NCI Omnibus R21)

C. Contributions to Science

1. Structural studies and elucidation of drug-binding sites: HIV-1 integrase

As a postdoctoral fellow and as an independent investigator I have applied innovative strategies in drug discovery to design novel HIV-1 integrase (IN) inhibitors. We were the first team to use pharmacophore models to identify IN inhibitors, the first to use photoaffinity labeling technologies to identify drug-binding sites on IN, the first to selectively target the viral LTR substrate for blocking viral integration, the first to use the NCI database of active compounds to identify inhibitors, the first to solve the co-crystal structure of ASV IN with, Y3, a naphthalene disulfonate that we originally identified as an HIV-1 IN inhibitor, and the first to show that MAP30 inhibits viral replication by a new mechanism independent of IN. My laboratory was the first to use 3D computational database searching to dock the entire NCI open database onto the Y3 binding site, leading to the identification of new IN inhibitors. We were the first team to synthesize two-metal binding diketoacids and the first to develop a novel "sequence walk" strategy to discover peptide-based IN inhibitors. Finally, my team was the first to identify an allosteric drug-binding site on IN that is important for IN multimerization, LEDGF/p75 binding, and amenable to high throughput. This study was the first report of uncoupling the 3'-processing reaction from the strand transfer that was featured on the cover of PNAS. Lastly, I edited the first comprehensive book on HIV-1 IN.



a. Drake RR, **Neamati N**, Hong H, Pilon AA, Sunthankar P, Hume SD, Milne GW, Pommier Y. Identification of a nucleotide binding site in HIV-1 integrase. *Proc Natl Acad Sci U S A* 1998, 95, (8), 4170-5. PMID: 9539708; PMCID: 22460.
b. Lubkowski J, Yang F, Alexandratos J, Wlodawer A, Zhao H, Burke TR, **Neamati N**, Pommier Y, Merkel G, Skalka AM, Structure of the catalytic domain of avian sarcoma virus integrase with a bound HIV-1 integrase-targeted inhibitor. *Proc Natl Acad Sci U S A* 1998, 95, (9), 4831-6. PMID: 9560188; PMCID: 20173.
c. Wang YX, **Neamati N**, Jacob J, Palmer I, Stahl SJ, Kaufman JD, Huang PL, Winslow HE, Pommier Y, Wingfield PT, Lee-Huang S, Bax A, Torchia DA. Solution structure of anti-HIV-1 and anti-tumor protein MAP30: structural insights into its multiple functions. *Cell* 1999, 99, (4), 433-42. PMID: 10571185.
d. Al-Mawsawi LQ, Fikkert V, Dayam R, Witvrouw M, Burke TR, Borchers CH, **Neamati, N**. Discovery of a small-molecule HIV-1 integrase inhibitor-binding site. *Proc Natl Acad Sci U S A* 2006**,** 103, (26), 10080-5. PMID: 16785440; PMCID: 1502509.

2. Structure and ligand-based drug design

The primary aim of my laboratory is to accelerate the pace of drug discovery through innovative approaches in medicinal chemistry. We are a leading laboratory in computer-aided drug design and ADMET-guided lead optimization. My laboratory routinely performs in-depth chemoinformatics coupled with bioinformatics analyses to design and optimize lead compounds against novel targets. My team has in place a variety of software packages as well as the expertise to perform multidimensional analyses. We continuously utilize cutting-edge technologies to design, synthesize, optimize, and validate small-molecule inhibitors. Because my goal is clinical translation I have in place a comprehensive program to perform in-depth mechanistic and preclinical studies of the most promising compounds.

a. **Neamati N**, Hong H, Mazumder A, Wang S, Sunder S, Nicklaus MC, Milne GW, Proksa B, Pommier Y. Depsides and depsidones as inhibitors of HIV-1 integrase: discovery of novel inhibitors through 3D database searching. *J Med Chem* 1997*, 40*, 942-951. PMID: 9083483.
b. Dayam R, Sanchez T, Clement O, Shoemaker R, Sei S, **Neamati N**. The beta-diketoacid pharmacophore hypothesis 1. The discovery of a novel class of HIV-1 integrase inhibitors. *J Med Chem* 2005*, 48,* 111-120. PMID: 15634005.
c. Dayam R, Aiello F, Deng J, Wu Y, Garofalo A, Chen X, **Neamati N.** Discovery of small molecule integrin αvβ3 antagonists as novel anticancer agents. *J Med Chem* 2006, 49, (15), 4526-4534. PMID: 16854058.
d. Zawahir Z, Dayam R, Deng J, Pereira C, **Neamati N**. Pharmacophore guided discovery of small molecule human apurinic/ apyrimidinic endonuclease 1 inhibitors. *J Med Chem* 2009, 52, 20-32. PMID: 19072053.

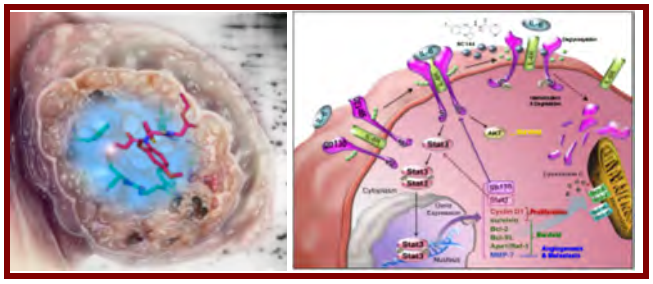
3. Medicinal chemistry (lead identification, optimization, and scale-up)

In-depth knowledge of medicinal chemistry is essential for a successful drug discovery program. My laboratory has applied modern synthetic medicinal chemistry to a variety of our projects. Moreover, we have developed and validated several original high throughput screening assays for novel targets and have completed a full screening campaign resulting in the identification of lead compounds that are amenable for further optimization. Most of these novel chemical entities have been published in over 40 manuscripts in the *J. Med. Chem*. resulting in 30 patent applications covering composition of matter and use.

a. Long YQ, Jiang XH, Dayam R, Sanchez T, Shoemaker R, Sei S, **Neamati, N.** Rational design and synthesis of novel dimeric diketoacid-containing inhibitors of HIV-1 integrase: implication for binding to two metal ions on the active site of integrase. *J Med Chem* 2004*, 47*, 2561-2573. PMID: 15115398.
b. Chen X, Plasencia C, Hou Y, **Neamati N**. Synthesis and biological evaluation of dimeric RGD peptide-paclitaxel conjugate as a model for integrin targeted drug delivery. *J Med Chem* 2005*, 48, 1098-1106.* PMID: 15715477.
c. Gundla R, Kazemi R, Sanam R, Muttineni R, Jagarlapudi SARP, Dayam R, **Neamati N**. Discovery of novel small-molecule inhibitors of human epidermal growth factor receptor: combined ligand and target-based approach. *J Med Chem* 2008, 51(12), 3367-3377.
d. Millard M, Gallagher JD, Olenyuk BZ, **Neamati N**. A selective mitochondrial-targeted chlorambucil with remarkable cytotoxicity in breast and pancreatic cancers. *J Med Chem* 2013*,* 56, 9170-79. PMID: 24147900.

4. Identification of first-in-class orally active small-molecule inhibitors

During the past several years my laboratory has identified multiple first-in-class small molecule compounds against various targets. We discovered an orally active protein disulfide isomerase (PDI) inhibitor for the treatment of ovarian cancer. PDI has a key role in maintaining cellular homeostasis by mediating oxidative protein folding. PDI is highly up-regulated in select cancers and its inhibitors are expected to be quite useful to treat these cancers. Another novel target for cancer treatment is gp130 that is a hub for cytokine signaling and mediates cancer progression. For the first time, we discovered that inhibition of gp130 activity offers a potential and promising approach to cancer therapy. In collaboration with Dr. An's laboratory, we demonstrated that VprBP possesses an intrinsic protein kinase activity and is capable of phosphorylating histone H2A on threonine 120 (H2AT120p) in the nucleosome. We identified the first-in-class inhibitor of this kinase as novel cancer therapeutics. More recently, we discovered a series of novel CXCR2 inhibitors targeting the tumor microenvironment. We are performing extensive preclinical studies and lead optimization campaigns on all these novel small-molecule inhibitors in patient-derived xenograft (PDX) and genetically engineered mouse models to select compounds for IND enabling studies.



a. Xu S, Butkevich AN, Yamada R, Zhou Y, Debnath B, Duncan R, Zandi E, Petasis NA, **Neamati, N**. Discovery of an orally active small-molecule irreversible inhibitor of protein disulfide isomerase for ovarian cancer treatment. *Proc Natl Acad Sci U S A* 2012, 109, 16348-16353. PMID: 22988091; PMCID: 3479552.
b. Xu S, Grande F, Garofalo A, **Neamati N**. Discovery of a novel orally active small-molecule gp130 inhibitor for the treatment of ovarian cancer. *Mol Cancer Ther* 2013, 12, 937-949. PMID: 23536726
c. Kim K, Kim JM, Kim JS, Choi J, Lee YS, **Neamati N**, Song JS, Heo K, An W. VprBP has intrinsic kinase activity targeting histone H2A and represses gene transcription. *Molecular Cell* 2013, 52, 459-67. PMID: 24140421; PMCID: 3851289.
d. Ha H, Bensman T, Ho H, Beringer PM, **Neamati N**. A novel phenylcyclohex-1-enecarbothioamide derivative inhibits CXCL8-mediated chemotaxis through selective regulation of CXCR2-mediated signalling. *Br J Pharmacol* 2014, 171, 1551-65. PMCID: PMC3954492

5. Innovative pharmacological probes and drug candidates targeting CXCR4 and CXCR2

To ensure clinical translation of my laboratory's drug candidates, I have built a robust preclinical pharmacology team capable of evaluating safety and efficacy of our novel CXCR2 and CXCR4 inhibitors. During the past several years we have performed extensive lead optimization and have selected a series of compounds for in-depth mechanistic and preclinical studies. For the lead compounds we perform ADMET-guided lead optimization coupled with preclinical PK/PD and efficacy studies in mice. Our lead compounds are suitable as

pharmacological probes to interrogate the role of CXCR2 and CXCR4 in cancer progression and as innovative therapeutics to treat select cancers.

a. Aboye T L, Ha H, Majumder S, Christ F, Debyser Z, Shekhtman A, **Neamati N**, Camarero JA. Design of a novel cyclotide-based CXCR4 antagonist with anti-human immunodeficiency virus (HIV)-1 activity. *J Med Chem* **2012,** 55, 10729-34.
b. Debnath B, Xu S, Grande F, Garofalo A, **Neamati N**. Small molecule inhibitors of CXCR4. *Theranostics* **2013,** 3, 47-75.
c. Ha H, **Neamati N**. Pyrimidine-based compounds modulate CXCR2-mediated signaling and receptor turnover. *Mol Pharm* **2014,** 11, 2431-41.
d. Ha H, Debnath B, Odde S, Bensman T, Ho H, Beringer PM, **Neamati N**. Discovery of novel CXCR2 inhibitors using ligand-based pharmacophore models. *J Chem Inf Model* **2015**.

Complete list of publications: >220 peer-reviewed publications, 30 book chapters, H-index=54

D. Research Support

Ongoing Research Support

Neamati, N (PI) 11/1/13 - 10/31/15
W81XWH-14-1-0001, DOD, Lung Cancer Research Program (LCRP) Concept Award
Title: Development of novel SHMT2 inhibitors for lung cancer treatment
Goal of this project is to perform preclinical studies of novel SHMT2 inhibitors in mice models of lung cancer.

Neamati, N (PI) 9/1/11 – 5/31/15
W81XWH-11-1-0430, DOD, Breast Cancer Research Program (BCRP) Idea Award
Title: Design of GRP78 inhibitors as novel therapeutics for breast cancer
The major goal of this project is to study preclinical development of our GRP78 inhibitors as single agents and combination in xenograft mouse models of human breast cancer.

Neamati, N (PI) 6/1/14 – 5/31/16
W81XWH-14-1-0172, DOD (OC130519), Ovarian Cancer Research Program (OCRP) Idea Award
Title: PDI Co-amplified Genes in Ovarian Cancer
The goal of this project is to validate a series of genes co-expressed with PDI in various tissue microarray samples and fresh frozen tissues.

Neamati (PI) 1/15/15-1/14/20
R01 CA190498 NIH
Title: gp130 as a novel therapeutic target in ovarian cancer
The goal of this project is to determine the significance of prognostic and predictive importance of gp130 as a biomarker in EOC, and assess the effect of its inhibition on patient sample derived tumor growth.

Neamati (PI) 6/15/15-6/14/20
R01 CA193690-01 NIH
Title: Efficacy of PDI inhibitors in glioblastoma
The goal of this project is to validate the role of PDI in GBM progression, resistance to chemotherapy, and to demonstrate safety and efficacy of our novel PDI inhibitors in PDX models of GBM.
R01 CA193690-01

Neamati (PI) 7/1/15-6/30/20
R01 CA188252-01 NIH
Title: ROS-targeted therapy for pancreatic cancer
The goal of this project is to perform in-depth preclinical studies on a series of novel small-molecule ROS-inducers in PDX models of pancreatic cancer.

Recently Completed

Neamati, N (PI) 9/30/07 - 7/31/13
R01 CA120188, NIH/NCI
Title: Integrin αvβ3 targeted drug design, delivery, and imaging

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Prados, Michael

eRA COMMONS USER NAME (credential, e.g., agency login): PRADOSM

POSITION TITLE: Professor in Residence, Department of Neurological Surgery

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
L.S.U. School of Medicine	M.D.	06/74	Medicine
L.S.U. School of Medicine	Intern	06/75	Internal Medicine
Earl K. Long Hospital	Resident	06/77	Internal Medicine
Tulane School of Medicine	Fellow	06/84	Pulmonary Medicine
University of California San Francisco	Fellow	06/87	Neuro-Oncology

A: Personal Statement

I have been involved in clinical and translational research in early phase clinical trials for both children and adults with CNS malignancies since 1985. I have led as Project Leader (the North American Brain Tumor Consortium) or co-Project Leader (the Adult Brain Tumor Consortium) for 20 years. I had been the institutional Principal Investigator of the UCSF Member Institution for the Pediatric Brain Tumor Consortium for many years. I currently am Project Leader of the Ivy Foundation Early Phase Clinical Trials Consortium (7 member institutions) and Project Leader for the Pacific Pediatric Neuro-Oncology Consortium (11 member institutions). I am the Program Leader for the Neurological Oncology Program for the Helen Diller Comprehensive Cancer Center, and previously was the Director of Translational Research in Neuro-Oncology. In addition, I am the Clinical co-Leader of the UCSF Brain Tumor SPORE grant, and co-leader of the Clinical and Statistical Core, Administrative Core, and Project 3 co-leader within that grant. As such, given my leadership roles, and clinical/translational research, I am qualified to participate in this research project.

B. Positions and Honors

Positions and Employment

1977-1978	Instructor, Internal Medicine, Internal Medicine, L.S.U. School of Medicine (Earl K. Long Hospital)
1979-1982	Assistant Professor, Internal Medicine , Internal Medicine, L.S.U. School of Medicine (Earl K. Long Hospital)
1984-1985	Assistant Clinical Director, Pulmonary Medicine, Internal Medicine, Tulane School of Medicine (Tuoro Hospital)
1985-1987	Clinical Instructor/Assistant Research Physician in Neurosurgery/Neuro-Oncology , Neurosurgery, University of California San Francisco
1988-1991	Assistant Clinical Professor in Neurosurgery/ Neuro-Oncology , Neurosurgery, University of California San Francisco
1988-1989	Acting Head: Neuro-Oncology Service, Neurosurgery, University of California San Francisco
1989-2005	Head, Neuro-Oncology Service, Neurosurgery, University of California San Francisco
1991-1995	Associate Clinical Professor in Neurosurgery/Neuro-Oncology , Neurosurgery, University of California San Francisco
1995-	Professor, In Residence in Neurosurgery/Neuro-Oncology , Neurosurgery, University of California San Francisco
2001-	Charles Wilson Professor of Neurological Surgery, Neurosurgery, University of California San Francisco
2005-2013	Director, Division of Translational Research in Neuro-Oncology, Neurosurgery, University of California San Francisco
2011-	Program Leader, Neurological Oncology Program, UCSF Helen Diller Comprehensive Cancer Center

Other Experience and Professional Memberships

1979-	American Society of Clinical Oncology
1995-	Society of Neuro-Oncology

Honors

Clinical Excellence Award 1997; Society of Neuro-Oncology
Victor Levin Award 2014; Society of Neuro-Oncology

C. Contribution to Science

1. My clinical research focus is on early phase clinical trials in adults and children. I have been involved in many projects linked to clinical trials and have sought to bring new approaches and therapeutics to patients with malignant CNS tumors. Within this context, we have sought to collaborate with other investigators around the country, in consortia related research, as well as conducting investigator-IND trials, and pharmaceutical company sponsored studies. The three publications cited below are examples of each. Lamborn et al is a summary of many clinical trials conducted by the North American Brain Tumor Consortium (NABTC) which I led as Project Leader for 15 years. The trial by Prados et al is an example of a multi-institutional study sponsored by industry which ultimately led towards Accelerated approval for bevacizumab in relapsed glioblastoma. The Clarke et al study was a single institution, investigator-initiated IND study conducted at UCSF.

Lamborn KR, Yung WK, Chang SM, Wen PY, Cloughesy TF, DeAngelis LM, Robins HI, Lieberman FS, Fine HA, Fink KL, Junck L, Abrey L, Gilbert MR, Mehta M, Kuhn JG, Aldape KD, Hibberts J, Peterson PM, Prados MD. Progression-free survival: an important end point in evaluating therapy for recurrent high-grade gliomas. Neuro Oncol. 2008 Apr; 10(2):162-70. PMID 18356283

Prados M, Cloughesy T, Samant M, Fang L, Wen PY, Mikkelsen T, Schiff D, Abrey LE, Yung WK, Paleologos N, Nicholas MK, Jensen R, Vredenburgh J, Das A, Friedman HS. Response as a predictor of survival in patients with recurrent glioblastoma treated with bevacizumab. Neuro Oncol. 2011 Jan;13(1):143-51. PMID 21084434

Clarke JL, Molinaro AM, Phillips JJ, Butowski NA, Chang SM, Perry A, Costello JF, DeSilva AA, Rabbitt JE, Prados MD. A single-institution phase II trial of radiation, temozolomide, erlotinib and bevacizumab for initial treatment of glioblastoma. Neuro-Oncol 2014 July: 16 (7): 984-990. PMID 24637230

2. My translational research focus is to collaborate with bench scientists conducting late phase rodent studies, mostly with molecularly targeted agents, prior to clinical development. The Mueller et al study involved a novel cell cycle modulating agent (Wee-1) in preclinical models in children, which is now a phase-1 trial within the Children's Oncology Group. The Chen et al study evaluated different routes of CNS delivery of a nanoliposomal irinotecan construct, which is now being tested at UCSF as part of a phase-1 Investigator-IND study using convection-enhanced deliver. This strategy was first tested in the UCSF Brain Tumor SPORE grant. The Michaud et al study used one of the first available CDK4/6 inhibitors in a relevant brain tumor xenograft model. This was followed by a clinical phase-2 trial. Again, this strategy was part of the UCSF Brain Tumor SPORE grant.

Mueller S, Hashizume R, Yang X, Kolkowitz I, Olow AK, Phillips J, Smirnov I, Tom MW, Prados MD, James CD, Berger MS, Gupta N, Haas-Kogan DA: Targeting Wee1 for the treatment of pediatric high-grade gliomas. Neuro Oncol 2013; 16 (3): 352-360. PMID 24305702; PMCID: PMC 3922515

Chen PY, Ozawa T, Drummond DC, Kalra A, Fitzgerald JB, Kirpotin DB, Wei KC, Butowski N, Prados MD, Berger MS, Forsayeth JR, Bankiewicz K, James CD. Comparing routes of delivery for nanoliposomal irinotecan shows superior anti-tumor activity of local administration in treating intracranial glioblastoma xenografts. Neuro Oncol. 2013 Feb; 15(2):189-97. PMID: 23262509

Michaud K, Solomon DA, Oermann E, Kim JS, Zhong WZ, Prados MD, Ozawa T, James CD, Waldman T. Pharmacologic inhibition of cyclin-dependent kinases 4 and 6 arrests the growth of glioblastoma multiforme intracranial xenografts. Cancer Res. 2010 Apr 15; 70(8):3228-38.

3. I am also involved supporting biomarker development and epidemiology studies, primarily within the NIH/NCI TCGA funded effort and the UCSF Brain Tumor SPORE grant, as part of a large team science effort searching for clues as to causation and risk SNP's associated with brain tumor development. The Walsh et al manuscript is SPORE related, and the Brennan et al manuscript from the TCGA.

Walsh KM, Rice T, Decker PA, Kosel ML, Kollmeyer T, Hansen HM, Zheng S, McCoy LS, Bracci PM, Anderson E, Hsuang G, Wiemels JL, Pico AR, Smirnov I, Molinaro AM, Tihan T, Berger MS, Chang SM, Prados MD, Lachance DH, Sicotte H, Eckel-Passow JE, Wiencke JK, Jenkins RB, Wrensch MR. Genetic variants in telomerase-related genes are associated with an older age at diagnosis in glioma patients: evidence for distinct pathways of gliomagenesis. Neuro Oncol. 2013 Jun 3. PMID: 23733245

Brennan CW, Verhaak RG, McKenna A, Campos B, Noushmehr H, Salama SR, Zheng S, Chakravarty D, Sanborn JZ, Berman SH, Beroukhim R, Bernard B, Wu CJ, Genovese G, Shmulevich I, Barnholtz-Sloan J, Zou L, Vegesna R, Shukla SA, Ciriello G, Yung WK, Zhang W, Sougnez C, Mikkelsen T, Aldape K, Bigner DD, Van Meir EG, Prados M, Sloan A, Black KL, Eschbacher J, Finocchiaro G, Friedman W, Andrews DW, Guha A, Iacocca M, O'Neill BP, Foltz G, Myers J, Weisenberger DJ, Penny R, Kucherlapati R, Perou CM, Hayes DN, Gibbs R, Marra M, Mills GB, Lander E, Spellman P, Wilson R, Sander C, Weinstein J, Meyerson M, Gabriel S, Laird PW, Haussler D, Getz G, Chin L. The somatic genomic landscape of glioblastoma. Cell. 2013 Oct 10; 155(2):462-77. PMID: 24120142

Complete list of published works in PubMed central:
http://www.ncbi.nlm.nih.gov/pubmed/?term=Michael+Prados

D. Research Support

Ongoing Research Support

P30 CA082103-15 McCormick (PI) 08/05/1999 – 05/31/2017

Cancer Center Support Grant
The Cancer Center Support Grant provides support for administration and infrastructure for the UCSF Comprehensive Cancer Center.
Role: Program Leader

Clinical Trial Consortium Prados (PI) 12/01/2009 – 11/30/2017
Ivy Foundation Early Phase Clinical Trials Consortium
The overall goal of the Consortium is to significantly increase the efficiency of therapeutic trials, increase the likelihood of success, and minimize exposure of drugs to patients with little chance of success. We will achieve this goal by using small sample size (10-15 patients) phase-2 trials giving therapeutic agents to patients prior to and following surgery.
Role: PI

P50 CA097257-13 Berger (PI) 09/20/2002 – 08/31/2018
Brain Tumor SPORE Grant (Renewal)
This UCSF Brain Tumor SPORE renewal grant has 4 overall specific objectives: 1) to identify factors that contribute to the likelihood of surviving brain cancer; 2) to identify spectroscopic, non-invasively derived imaging parameters and linked tissue biomarkers that can help predict recurrence and outcome in patients with low grade glioma; 3) to develop improved therapies for pediatric brain tumors harboring BRAF mutations; and 4) to improve the immunotherapy of brain cancer.

Project 3 Nicolaides/Prados
Novel Approaches for Improving Pediatric BRAFV600E Glioma Patient Outcomes
This is a highly translational project that will further investigate and see to the clinical testing of a targeted therapeutic treatment of children with a specific, genetically-defined type of glioma. Other than surgery and radiation, there are currently no effective treatments for glioma in children, and the effective treatments only provide short-term relief from the cancer, while substantially contributing to patient morbidity. The research proposed here will see to the rigorous preclinical and clinical testing of novel treatments for this cancer patient population, and that hold substantial promise for improving outcomes for children with glioma.
Role: Co-PI

Core C Prados/Molinaro
This Biostatistics and Clinical Core supports the efforts of 4 Projects designed to study the biology, incidence, and epidemiology of brain tumors (high grade and low grade) using those results to "translate" into clinical trials. The Core will supply statistical and clinical leadership and input towards those efforts.
Role Co-PI

Core D Berger/Pieper/Prados
The Administrative Core of the UCSF Brain Tumor SPORE has been created to supervise the activities of the UCSF Brain Tumor SPORE and to provide fiscal management, administrative support, and the framework by which researchers can communicate and interact. Aims of the Administrative Core will be to: 1) Evaluate research progress; 2) Provide fiscal management; 3) Provide administrative support; 4) Facilitate communication between SPORE investigators; and 5) Assist in compliance. The Administrative Core will be used by all Projects and Cores in the SPORE and will be responsible for assuring compliance and scientific integrity of all components of the SPORE.
Role: Co-PI

PLGA Foundation Prados (PI) 12/01/2013 – 11/30/2016
Pediatric Low Grade Astrocytoma Foundation: Determinants of response and resistance in pediatric low
The overall goal is to establish which PLGGs are best treated with everolimus, how activation of BRAF modifies response to everolimus, and which personalized combination therapies will prevent emergence of resistance.
Role: PI

Genentech, Inc. Nicolaides (PI) 05/31/2013 – 05/31/2018

PNOC-002: Safety, Phase 0, and Pilot Efficacy Study of Vemurafenib, an Oral Inhibitor of BRAFV600E, in Children with Recurrent/Refractory BRAFV600E-Mutant Gliomas
This study will try to define the safe dose of vemurafenib to be used in children with astrocytomas. Subsequently, the study will attempt to document vemurafenib drug levels within surgically resected tumor samples. If drug levels are found to meet our goals, an expanded cohort will be opened to measure efficacy of this drug in children with recurrent tumors.
Role: Project Leader

PBTF Prados (PI) 01/01/2015 – 12/31/2016
Opportunity Award
This Pediatric Brain Tumor Foundation award supports the activities of the Operations Office for the Pacific Pediatric Neuro-Oncology Consortium (PNOC).
Role: PI

Completed Research Support

PNOC Foundation Prados (PI) 01/01/2015 – 12/31/2015
Operations Office Support Grant
This award supported the activities of the Operations Office for the Pacific Pediatric Neuro-Oncology Consortium (PNOC).
Role: PI

U01 CA81457 Boyette (PI) 04/01/2009 – 03/31/2014
St. Jude Children's Research Hospital (NIH prime)
UCSF collaborated with the Pediatric Brain Tumor Consortium (PBTC) to achieve its Consortium goals and contributed to its scientific agenda to increase disease-free and overall survival in children with brain tumors.
Role: UCSF Member Institution Principal Investigator

U01 CA137443 Grossman/Prados 01/01/2009 – 12/31/2013
Adult Brain Tumor Consortium (ABTC)
The major goals of the Operations Office were to: coordinate all activities of the American Brain Tumor Consortium (ABTC); coordinate protocol development; to coordinate Phase I/II trials; monitor quality control and protocol performance; monitor reporting, analysis, data management; and coordinate central pathology review for all ABTC studies.
Role: Co-PI for Operations

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Prendergast, George C.	POSITION TITLE Professor, President & CEO
eRA COMMONS USER NAME PRENDERGASTG	

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	MM/YY	FIELD OF STUDY
University of Pennsylvania, Philadelphia PA	B.S.	1983	Biochemistry
Yale University, New Haven CT	M.S.	1984	Molecular Biophysics and Biochemistry
Princeton University, Princeton NJ	Ph.D.	1989	Molecular Biology

A. Personal Statement

The overall goal of my research has been to develop new molecular therapeutic principles ("genes to drugs"). Starting from early work on Myc and Ras function in cancer, my group developed a focus on modifier pathways affected by Bin1 and RhoB, two regulators of membrane dynamics we have found to widely modify the progression of cancer and other age-associated diseases. Our work on RhoB altered the mechanistic perspective on farnesyl transferase inhibitors (FTI) as Ras-targeting drugs, one of the first targeted signal transduction inhibitors to be tested in clinic. During the last decade, our work has revealed impacts of these modifier pathways on immunity, metabolics and angiogenesis in the tumor microenvironment. In our most productive direction to date, we discovered a general pathway of tumoral immune escape controlled by the Bin1-regulated enzyme IDO, an important immune checkpoint regulator, and pioneered genetics and pharmacology studies which validated IDO as a key regulator of immune escape and metastasis. We also discovered the IDO-related enzyme IDO2 which modulates the microenvironmental attitude to 'altered self' antigens in cancer and autoimmunity. Translationally, our NIH-supported small molecule inhibitor program established the preclinical foundation for IDO to be developed as a therapeutic target, with lead compounds now in multiple Phase II human trials. At present, we are now mainly focused on a new class of 'anti-checkpoint' agents that exhibit in vivo efficacy in autoimmune models.

To speed the kinetics of translation for innovations like these, I created an 'acapreneurial' organizational model for non-profit biomedical research as leader of the Lankenau Institute for Medical Research (LIMR). Our model

enhances the impact of basic science by integrating clinical researchers, laboratory investigators and biotech companies partnered by equity-barter in the same facility (www.limr.org). As one illustration, the first small molecule inhibitor of IDO was quickly translated to Phase I clinical trials through a biotech company (OncoRx) started at Lankenau and acquired by New Link Genetics Corporation. Both of the IDO drug development programs initiated at Incyte and BMS have their early roots from my former group at DuPont Pharmaceuticals before its sale moved DuPont scientists to Lankenau, BMS and Incyte where different classes of IDO inhibitors were subsequently developed based on our preclinical genetic and pharmacological validation studies. In pioneering this small molecule-based approach to empower antitumor immunity, which is now producing positive clinical data in human trials, we believe that IDO inhibition will offer a broad-based and cost-effective adjuvant strategy to improve the treatment of cancer and other diseases marked by chronic infection or sterile pathogenic inflammation. Our long-term goal is to apply our mechanistic insights to challenges faced by clinicians and patients, including to develop new therapeutics, inform trials recruitment, predict therapeutic responses and prognose outcomes.

B. Positions and Honors

Primary Positions

1989-1991 American Cancer Society Postdoctoral Fellow, HHMI & Dept. of Biochem., NYU Medical Center
1991-1993 Senior Research Biochemist, Merck Research Laboratories
1993-1997 Assistant Professor, The Wistar Institute
1997-1999 Associate Professor & Assistant Chair, Tumor Biology Group, The Wistar Institute
1999-2001 Senior Director, Cancer Research Group, DuPont Pharmaceuticals Company
2002- Professor, Lankenau Institute for Medical Research
2004- President & CEO, Lankenau Institute for Medical Research

Other Key Appointments

2006- Professor, Department of Pathology, Anatomy & Cell Biology, Sidney Kimmel Medical School, Thomas Jefferson University.
2006- Co-Director, Program in Cancer Cell Biology & Signaling, Kimmel Cancer Center, Thomas Jefferson University.

Selected Editorial and Grants Review Experience

1997-2005 Pathobiology-1/-2 Study Sections, USAMRMC Breast Cancer Research Program
2003-2005 Senior Editor, *Cancer Research*
2005-2010 Deputy Editor, *Cancer Research*
2006-2010 Chartered Member, NIH Drug Discovery and Molecular Pharmacology Study Section (DMP)
2010- Editor-in-Chief, *Cancer Research*
2015- Chartered Member, CPRIT Scientific Review Council, Basic Cancer Research-1 Committee

Start-up Companies

2003-2005 Co-founder and CEO, OncoRx Inc. *(IDO therapy company sold to New Link Genetics 2005)*
2007-2014 Founder and CEO, Lankenau Chemical Genomics Center Inc.*(chemical diversity depot)*
2007- Founder, CEO and Chairman, Lankenau Development Inc. *(business development subsidiary)*
2013- Director, Meditope Biosciences Inc. *(antibody technology platform)*

Selected Honors

1980-83 Benjamin Franklin Scholar (top 5% of undergraduate class), University of Pennsylvania
1983 B.A. *magna cum laude* with Distinction in Biochemistry, University of Pennsylvania
1984 IBM University Prize Fellowship
1989 American Cancer Society Postdoctoral Fellowship
1995 American Cancer Society Junior Faculty Award
1995 Pew Scholar in the Biomedical Sciences Award
2008 Special Achievement Award in Cancer Research, Chinese Society for Clinical Oncology

2008 Designated One of the 250 Historically Most Influential Alumni of Princeton University http://paw.princeton.edu/issues/2008/01/23/pages/9532/index.xml?page=1&.
2011 Translational Medicine Award, Shanghai Translational Medicine Forum, Shanghai China
2011 Highlighted 'In the Pipeline' Project, DoD Breast Cancer Research Program Annual Report
2011 European Academy of Tumor Immunology
2012 Inventor of the Year, Sidney Kimmel Cancer Center, Thomas Jefferson University
2014 Highlighted 'In the Pipeline' Project, DoD Breast Cancer Research Program Annual Report
2016 The Havens Endowed Chair in Biomedical Research, Lankenau Institute for Med Research

C. Selected Peer-Reviewed Publications (Google Scholar h index=66; pubs with >100 citations=47/282)
From total of 162 peer-reviewed pubs, 3 edited books, 42 issued or pending patents
*Co-senior authors marked by asterisks**

1. Sakamuro D, Elliott K, Wechsler-Reya R and Prendergast GC. (1996). BIN1 is a novel MYC-interacting protein with features of a tumor suppressor. Nature Genet 14, 69-77.
2. Muller AJ, DuHadaway JB, Donover PS, Sutanto-Ward E, Prendergast GC (2005). Inhibition of indoleamine 2,3-dioxygenase, a target of the cancer suppression gene *Bin1*, potentiates cancer chemotherapy. Nature Med 11, 312-319.
3. Chang MY, Boulden J, Sutanto-Ward E, DuHadaway JB, Katz JB, Wang L, Meyer TB, Soler AP, Muller AJ and Prendergast GC. (2007). Bin1 ablation increases cancer susceptibility during aging, particularly lung cancer. Cancer Res 67, 7605-7612.
4. Hou DY, Muller AJ, Sharma M, DuHadaway J, Banerjee T, Johnson M, Mellor AL, Prendergast GC, Munn DH (2007). Inhibition of IDO in dendritic cells by stereoisomers of 1-methyl-tryptophan correlates with anti-tumor responses. Cancer Res 67, 792-801.
5. Metz R, DuHadaway JB, Kamasani U, Laury-Kleintop L, Muller AJ, Prendergast GC (2007). Novel tryptophan catabolic enzyme IDO2 is the preferred biochemical target of the antitumor IDO inhibitory compound D-1MT. Cancer Res 67, 7082-7087.
6. Kumar S, Jaller D, Patel B, LaLonde JM, DuHadaway JB, Malachowski WP, Prendergast GC and Muller AJ. (2008). Structure based development of phenylimidazole-derived inhibitors of indoleamine 2,3-dioxygenase. J Med Chem 51, 4968-4977.
7. Muller AJ, Sharma MD, Chandler PR, DuHadaway JB, Everhart M, Johnson BA, Dahler DJ, Pihkala J, Soler AP, Munn DH, Prendergast GC*, Mellor AL* (2008). Chronic inflammation that facilitates tumor progression creates local immune suppression by inducing indoleamine 2,3-dioxygenase. PNAS 105, 17073-8.
8. Witkiewicz AK, Costantino CL, Metz R, Muller AJ, Prendergast GC, Yeo CJ, Brody JR. (2009). Genotyping and expression of IDO2 in human pancreatic cancer: a novel, active target. J Amer Coll Surg 208, 781-787.
9. Muller AJ, DuHadaway JB, Chang MY, Ramalingam A, Sutanto-Ward E, Boulden J, Mandik-Nayak L, Gilmour SK, Prendergast GC. (2010). Non-hematopoietic expression of IDO is critical for inflammatory tumor promotion. Cancer Immunol Immunother 59, 1655-1663.
10. Smith C, Chang MY, Parker K, Beury D, DuHadaway JB, Flick H, Boulden J, Sutanto-Ward E, Soler AP, Laury-Kleintop L, Mandik-Nayak L, Metz R, Ostrand-Rosenberg S, Prendergast GC*, Muller AJ.* (2012). IDO is a nodal pathogenic driver of lung cancer development and metastasis. Cancer Discov 2, 722-735.
11. Metz R, Rust S, DuHadaway JB, Mautino MR, Munn DH, Vahanian NN, Link CJ and Prendergast GC. (2012). IDO inhibits a tryptophan sufficiency signal needed to stimulate mTOR: a novel IDO effector pathway targeted by 1-methyl-D-tryptophan. OncoImmunology 1, 1460-1468.
12. Chang MY, Boulden J, Valenzano MC, Soler AP, Muller AJ, Mullin JM and Prendergast GC. (2012). Bin1 attenuation suppresses inflammatory colitis by enforcing intestinal barrier function. Dig Dis Sci 57, 1813-1821.
13. Li J, Ward KM, Zhang D, Dayanandam E, DeNittis AS, Prendergast GC and Ayene IS. (2013). A bioactive probe of the oxidative pentose phosphate cycle: novel strategy to reverse radioresistance in glucose deprived human colon cancer cells. Toxicol. In Vitro 27, 367-377.
14. Trabanelli S, Očadlíková D, Ciciarello M, Salavestrini V, Lecciso M, Camilla J, Metz R, Evangelisti C, Laury-Kleintop L, Romero P, Prendergast GC, Curti A, Lemoli RM. (2014). SOCS3-independent expression of IDO2 supports homeostatic generation of Treg cells by human dendritic cells. J Immunol 192, 1231-1240.

15. Metz R, Smith C, DuHadaway JB, Chandler P, Baban B, Merlo LMF, Pigott E, Keough MP, Rust S, Mellor AL, Mandik-Nayak L, Muller AJ and Prendergast GC. (2014). IDO2 is critical for IDO1-mediated T cell regulation and exerts a non-redundant function in inflammation. Int Immunol 26, 357-367.
16. Merlo LMF, Pigott E, DuHadaway JB, Grabler S, Metz R, Prendergast GC and Mandik-Nayak L. (2014). IDO2 is a critical mediator of autoantibody production and inflammatory pathogenesis in a mouse model of autoimmune arthritis. J Immunol 192, 2082-2090. *Cover article*
17. Bessede A, Gargaro M, Pallotta T, Matino D, Servillo G, Brunacci C, Bicciato B, Mazza EMC, Macchiarulo A, Vacca C, Iannitti R, Tissi L, Volpi C, Belladonna ML, Orabona C, Bianchi R, Lanz T, Platten M, Della Fazia MA, Piobbico D, Zelante T, Funakoshi H, Nakamura T, Gilot D, Denison MS, Guillemin GJ, DuHadaway JB, Prendergast GC, Metz R, Geffard M, Boon L, Romani L, Veyret B, Grohmann U, Puccetti, P and Fallarino F. (2014). Tryptophan catabolites as ligands of the aryl hydrocarbon receptor allow transition from endotoxin susceptibility to tolerance. Nature 511, 184-190.
18. Thomas S, Mercado JM, DuHadaway J, DiGuilio K, Mullin JM and Prendergast GC. (2015). Novel colitis immunotherapy targets Bin1 to improve colon cell barrier function. Dig. Dis. Sci., in press. PMID: 26195312.
19. DuHadaway JB and Prendergast GC. (2016). Antimetabolite TTL-315 selectively kills glucose-deprived cancer cells and enhances responses to cytotoxic chemotherapy in preclinical models of cancer. Oncotarget, in press.

Significant Reviews & Perspectives

1. Muller AJ and Prendergast GC. (2005). Marrying immunotherapy with chemotherapy: why say IDO? Cancer Res. 65, 8065-8068.
2. Prendergast GC and Jaffee EM. (2007). Cancer immunologists and cancer cell biologists: why we didn't talk then but need to now. Cancer Res 67, 3500-3505.
3. Prendergast GC. (2008). Immune escape as a fundamental trait of cancer: focus on IDO. Oncogene 27, 3889-3900.
4. Prendergast GC, Metz R and Muller AJ. (2010). Towards a genetic definition of 'cancer-associated' inflammation: role of the IDO pathway. Amer J Pathol 176, 2082-2087.
5. Prendergast GC. (2011). Why tumours eat tryptophan. Nature 478, 192-194.
6. Monteleone L, Sawyers C, Abate-Shen C, Anderson K, Barker A, Foti M, Baselga J, Berger N, Jemal A, Li C, Mardis E, Neumann P, Pardoll D, Prendergast GC, Reed J and Weiner G. (2013). AACR Cancer Progress Report 2013. Clin. Cancer Res. 19 (Supplement 2), S1-S86.
7. Prendergast GC, Smith C, Thomas S, Mandik-Nayak L, Laury-Kleintop LD, Metz R and Muller AJ. (2014). Indoleamine 2,3-dioxygenase pathways in pathogenic inflammation and immune escape in cancer. Cancer Immunol Immunother 63, 721-735. *Cover article*
8. Prendergast, G.C., Metz, R., Muller, A.J., Merlo, L.M.F. and Mandik-Nayak, L. (2014). IDO2 in immunomodulation and autoimmune disease. Front Immunol. 5, 585-590.
9. Prendergast, G.C. (2015). A perspective on cancer as an abortive autoimmune response to altered-self. Cancer Res. 75, 3-4.

Edited Books

1. Prendergast GC. (2004). Molecular Cancer Therapeutics: Strategies for Drug Discovery and Development (Book Editor). New York: John Wiley & Sons. 351 pg. (Reviewed in N. Engl. J. Med. 352, 422-423 [2005].)
2. Prendergast GC and Jaffee EM. (2007). Cancer Immunotherapy: Immune Suppression and Tumor Growth, 1st edition (Book Editors). New York: Academic Press. 428 pg. (Reviewed in N. Engl. J. Med. 358, 1764-1765 [2008]).
3. Prendergast GC and Jaffee EM. (2013). Cancer Immunotherapy: Immune Suppression and Tumor Growth, 2nd edition (Book Editors). New York: Elsevier/Academic Press. In press.

D. Current Research Support

NIH R01 CA109542 Prendergast, G.C. (PI) 7/11-6/16
Title: IDO inhibitors for combinatorial cancer treatment
Summary: Synthesis and characterization of small molecule inhibitors of IDO enzymes

Award: $1,669,525 (total direct costs)

NIH R01 CA191191 Prendergast, G.C. (PI) 7/15-6/20
Title: IDO2 targeting in pancreatic cancer
Summary: Genetic and pharmacological validation of IDO2 as a therapeutic target in pancreatic cancer
Award: $1,842,173 (total direct costs)

W.W. Smith Trust Prendergast, G.C. (PI) 9/13-8/18
Title: Translational Cancer Research Projects
Summary: Development of a predictive blood test for hospitalizable chemotherapy-induced nausea and other clinical prognostic tests
Award: $625,000 (total direct costs)

NIH P30 CA056036 Knudsen, K. (PI) 6/13-5/18
Title: Translational Research in Cancer
Summary: NCI Cancer Center Grant for Kimmel Cancer Center at Thomas Jefferson University (LIMR affiliate)
Award: $12,036 (annual direct costs)

OMB No. 0925-0001/0002 (Rev. 08/12 Approved Through 8/31/2015)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. DO NOT EXCEED FIVE PAGES.

NAME: **Brian M. Wolpin**

eRA COMMONS USER NAME (agency login): BWolpin6942

POSITION TITLE: Associate Professor of Medicine

EDUCATION/TRAINING:

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY
Wesleyan University, Middletown, CT	B.A.	05/1996	Molecular Biology & Biochemistry
Harvard Medical School, Boston, MA	M.D.	06/2001	Medicine
Brigham and Women's Hospital, Boston, MA	Residency	06/2004	Internal Medicine
Dana-Farber Cancer Institute, Boston, MA	Fellowship	06/2007	Medical Oncology
Harvard School of Public Health, Boston, MA	M.P.H.	05/2008	Epidemiology

A. Personal Statement

Dr. Wolpin has the necessary training, research experience, technical expertise, resources, and leadership to coordinate and perform the proposed work in this grant submission.

Background and training: I am a board-certified medical oncologist, who sees patients in the Gastrointestinal Cancer Clinic at Dana-Farber Cancer Institute (DFCI) with a focus on pancreatic cancer. I have a Masters of Public Health from Harvard School of Public Health (HSPH), where I received training in epidemiology, biostatistics, and study design. I completed post-doctoral training at DFCI with Dr. Charles Fuchs, after selection for the Training Program in Cancer Epidemiology fellowship award from HSPH (PI: Meir Stampfer). I was selected for a Howard Hughes Medical Institute extramural fellowship to study DNA repair mechanisms in breast cancer in the laboratory of Dr. David Livingston at DFCI during medical school. Therefore, I have extensive training in study design, biostatistics and conduct of molecular marker and translational studies in cancer.

Research experience, technical expertise, and resources: My research program is dedicated to the investigation of pancreatic ductal adenocarcinoma (PDAC) biology and treatment. I have built multiple human subject resources to facilitate investigation of blood-based markers, germline alterations, and somatic alterations in hundreds to thousands of subjects. I lead a highly productive collaboration of five prospective cohort studies that leverages prediagnostic blood specimens to identify novel circulating markers for PDAC. As part of this work, my group has developed extensive expertise in measuring and analyzing markers of altered metabolism. I serve as co-Principal Investigator for the Pancreatic Cancer Cohort Consortium, a multi-institutional NCI-based consortium studying inherited genetics of sporadic PDAC. We performed the first large-scale genome-wide interrogations of genetic variation and PDAC risk. Additionally, I lead a PDAC biospecimen bank at DFCI that collects patient data, blood specimens and tumor samples and is focused on identifying new prognostic and predictive biomarkers. I have extensive experience designing and leading phase 1 and 2 clinical trials for patients with PDAC. I am Principal Investigator of a translational trials coalition founded by the Lustgarten Foundation that includes several large academic cancer centers. Clinical trials run within this Coalition are focused on serial biospecimen collection to understand mechanisms of therapeutic response and resistance. I also serve as Medical Oncology Study Chair for ALLIANCE clinical trial A021501 that investigates new treatment approaches patients with borderline-resectable PDAC. Therefore, I have extensive experience in generating and analyzing large, complex, multi-dimensional datasets related to PDAC development and progression.

Scientific environment: My group is located at DFCI, in close proximity to Brigham and Women's Hospital, Harvard Medical School, HSPH, MIT, Broad Institute, and other Harvard hospitals. Therefore, I benefit from an outstanding scientific environment with excellence in patient care, study design, sample analyses, statistical methods, cancer biology, and high-throughput experimental and computational biology.

Leadership: I lead multiple large consortia focused on circulating and genetic markers in pancreatic cancer and have extensive experience bringing together large teams of investigators with varied backgrounds to study pancreatic cancer. This is evident is my leadership of local (e.g. DFCI PDAC biobank), regional (e.g. Harvard five cohort PDAC collaborative), and national (e.g. Pancreatic Cancer Cohort Consortium and Lustgarten Clinical Science Coalition) collaborations that require extensive team building, sample coordination, and multi-dimensional data analysis. I also hold multiple leadership positions related to clinical expertise in gastrointestinal cancer, including membership on the ALLIANCE Gastrointestinal Cancer Committee and NCCN Guidelines Committee for Pancreatic Adenocarcinoma. I am Medical Oncology Study Chair of ALLIANCE trial A021501 for patients with borderline-resectable PDAC. I also lead the Pancreas and Biliary Tumor Center at DFCI, which brings together clinical and research operations across the cancer center related to pancreatic cancer.

B. Positions and Honors

Positions:

2006-2007	Chief Resident, Brigham and Women's Hospital, Boston MA
2007-	Staff Physician, Gastrointestinal Cancer Center, Dana-Farber Cancer Institute, Boston, MA
2007-2009	Instructor in Medicine, Harvard Medical School, Boston, MA
2009-2015	Assistant Professor of Medicine, Harvard Medical School, Boston, MA
2013-	Co-Director, Pancreas and Biliary Tumor Center, Dana-Farber Cancer Institute, Boston, MA
2015-	Associate Professor of Medicine, Harvard Medical School, Boston, MA

Awards and Honors:

1994-1995	Burroughs-Wellcome Fund Undergraduate Research Grant, Wesleyan University
1995	Howard Hughes Medical Institute Undergraduate Research Fellowship, Wesleyan University
1995	Phi Beta Kappa, Early Induction, Wesleyan University
1996	High Honors, Undergraduate Thesis, Wesleyan University
1997	Preclinical Medical Student National Health Service Corps Fellowship
1999-2000	Howard Hughes Medical Institute Extramural Medical Student Research Fellowship
2001	John E. Thayer Scholarship, Harvard University
2007-2009	Training Program in Cancer Epidemiology Fellowship, Harvard School of Public Health
2007-2012	Loan Repayment Program Award, National Institutes of Health
2010-	Member, NCCN Pancreatic Adenocarcinoma Guidelines Committee
2011-2012	Member, NCI Pancreas Cancer Task Force
2011-2012	Study Chair, Cancer and Leukemia Group B protocol CALGB 81003, Metastatic PDAC
2011-	Co-Principal Investigator, NCI Pancreatic Cancer Cohort Consortium
2012-	Member, CALGB/ALLIANCE Gastrointestinal Cancer Committee

2014	Keynote Speaker, AACR Integrative Molecular Epidemiology Workshop
2014-2015	Editor, Pancreatic Cancer, *Hematology/Oncology Clinics of North America*
2014-2015	Member, External Advisory Board, Pancreatic Cancer, Ontario Institute for Cancer Research
2014-	Member, ASCO Scientific Program Committee, Cancer Prevention, Genetics, & Epidemiology
2015	George Canellos Award for Excellence in Clinical Investigation
2015-	Medical Oncology Study Chair, ALLIANCE protocol A021501, Borderline-resectable PDAC
2015-	Member, Pancreatic Cancer Action Network-AACR Career Development Award Scientific Review Committee
2015-	Member, Clinical and Translational Cancer Research Scientific Review Panel, Research Program of the Cancer Prevention and Research Institute of Texas (CPRIT)

C. Contributions to Science

1. Altered metabolism and pancreatic cancer: Studies suggested that diabetes was a risk factor for PDAC. However, 20-30% of patients develop diabetes in the several years prior to their cancer diagnosis, leading to controversy related to reverse causation. We used a well-characterized population with prospectively collected, prediagnostic blood samples to show for the first time that insulin resistance is both a classical risk factor and a paraneoplastic syndrome due to subclinical PDAC (Wolpin, 2013). We also demonstrated that PDAC risk was related primarily to severity of peripheral insulin resistance and not the degree of hyperglycemia. We have subsequently examined multiple other facets of insulin resistance to better characterize the at-risk metabolic phenotype. Most recently, we leveraged metabolomics (Townsend, 2013) to demonstrate that pancreatic tumors cause an elevation in circulating branched chain amino acids (BCAAs) in the 6-8 years before diagnosis (Mayers, 2014). We validated these findings in PDAC mouse models and showed that BCAAs were liberated from peripheral tissues in presence of early PDAC tumors. Thus, our work has opened new lines of inquiry into risk markers and cancer-induced metabolic alterations with utility for risk stratification and disease screening.

a. **Wolpin BM**, Bao Y, Qian ZR,..., Manson JE, Giovannucci EL, Fuchs CS. Hyperglycemia, insulin resistance, impaired pancreatic beta-cell function and risk of pancreatic cancer. *J Natl Cancer Inst*. 2013; 105(14):1027-1035. PMCID: 3714020

b. Bao Y, Giovannucci EL, Kraft P,..., Manson JE, Fuchs CS, **Wolpin BM**. A prospective study of plasma adiponectin and pancreatic cancer risk in five US cohorts. *J Natl Cancer Inst*. 2013;105(2):95-103. PMCID: 3545904

c. Townsend MK, Clish CB, Kraft P,..., Deik AA, Tworoger SS, **Wolpin BM**. Reproducibility of metabolomic profiles among men and women in two large cohort studies. *Clin Chem*. 2013;59(11):1657-67. PMCID: 3812240

d. Mayers JR, Wu C, Clish CB,..., Fuchs CS, Vander Heiden MG, **Wolpin BM**. Elevated circulating branched chain amino acids are an early event in pancreatic adenocarcinoma development. *Nature Medicine*. 2014;20(10):1193-8. PMCID: 4191991

2. Inherited genetic predisposition to pancreatic cancer: Moderate-penetrance mutations have been linked to PDAC familial syndromes. However, no large-scale studies had investigated inherited genetic variation and sporadic PDAC. As co-Principal Investigator of the Pancreatic Cancer Cohort Consortium (PanScan), I played a vital role in identifying the first known regions of the genome associated with sporadic PDAC risk. Most recently in the PanScan 3 study, we identified 5 new gene regions associated with sporadic PDAC, bringing the total to 9 regions identified in the PanScan studies. Several of these regions include genes that we are studying in greater detail to elucidate underlying biology. We identified that a PDAC-associated SNP in the first intron of *ABO* was in near complete LD with a single base deletion that defines *O* vs. non-*O ABO* alleles. ABO is a glycosyltransferase that forms the basis of transfusion medicine, but also dictates glycosylation patterns on surface epithelial cells throughout the gastrointestinal tract. In a series of studies, we have examined serologic and genotypic ABO blood types. We showed that non-O alleles confer higher PDAC risk and through genetic studies demonstrated that this risk is due to the degree of ABO enzyme function. We also showed that ABO blood type is not associated with risk of several other cancers, indicating a specific predisposition to PDAC.

a. **Wolpin BM**, Chan AT, Hartge P,..., Hunter DJ, Giovannucci EL, Fuchs CS. ABO blood group and the risk of pancreatic cancer. *J Natl Cancer Inst.* 2009;101(6): 424-431. PMCID: 2657095

b. **Wolpin BM**, Kraft P, Gross M,..., Zeleniuch-Jacquotte A, Hartge P, Fuchs CS. Pancreatic cancer risk and ABO blood group alleles: results from the pancreatic cancer cohort consortium. *Cancer Research.* 2010;

70(3):1015–23. PMCID: 2943735

c. **Wolpin BM**, Kraft PL, Xu M,..., Zeleniuch-Jacquotte A, Hartge P, Fuchs CS. Variant ABO blood group alleles, secretor status and risk of pancreatic cancer: results from the pancreatic cancer cohort consortium. *Cancer Epidemiol Biomarkers Prev*. 2010;19(12):3140-9. PMCID: 3005538

d. **Wolpin BM**, Rizzato C, Kraft P,..., Chanock S, Stolzenberg-Solomon RS, Amundadottir LT. Genome-wide association study identifies multiple susceptibility loci for pancreatic cancer. *Nature Genet.* 2014;46(9): 994-1000. PMCID: 4191666

3. Circulating markers and pancreatic cancer risk: We have had a long-running interest in defining new circulating markers that can be used for PDAC risk stratification in the general population. We are working to incorporate our findings into new risk models for sporadic PDAC (Klein, 2013).

a. **Wolpin BM**, Michaud DS, Giovannucci EL,..., Ma J, Pollak MN, Fuchs CS. Circulating insulin-like growth factor binding protein-1 and the risk of pancreatic cancer. *Cancer Res.* 2007;67(16):7923-8. PMID: 17699799

b. **Wolpin BM**, Ng K, Bao Y, ..., Manson JE, Giovannucci EL, Fuchs CS. Plasma 25-hydroxyvitamin D and risk of pancreatic cancer. *Cancer Epidemiol Biomarkers Prev*. 2012;21(1):82-91. PMCID: 3253914

c. Bao Y, Giovannucci E, Kraft P,..., Manson JE, Fuchs CS, **Wolpin BM**. Inflammatory Plasma Markers and Pancreatic Cancer Risk: a Prospective Study of 5 U.S. Cohorts. *Cancer Epidemiol Biomarkers Prev*. 2013;22(5):855-61. PMCID: 3650127

d. Klein AP, Lindström S, Mendelsohn JB,..., **Wolpin BM**, Yu H, Yu K, Zeleniuch-Jacquotte A, Chanock SJ, Hoover RN, Hartge P, Kraft P. An absolute risk model to identify individuals at elevated risk for pancreatic cancer in the general population. *PLoS One*. 2013;8(9):e72311. PMCID: 3772857

4. Determinants of survival in pancreatic cancer: Factors that impact survival of patients with PDAC are poorly understood. We are studying how altered metabolism, inherited genetic variation and somatic alterations impact patient survival. We demonstrated that patients with chronic obesity have shorter survival than normal weight patients (Yuan, 2013). We examined the impact of long-term diabetes and recent-onset paraneoplastic diabetes on survival, and showed that long-term diabetes is associated with reduced patient survival (Yuan, 2015). This reduction in survival could be due to increased comorbidities among long-term diabetics, but our work suggests that survival differences are due to more aggressive behavior of PDAC that develops in the setting of long-term diabetes. We are testing this hypothesis using a large tumor bank from DFCI patients and several other academic centers. In the first study of its kind, we also examined genome-wide inherited alterations, demonstrating several gene regions associated with PDAC survival (Wu, 2014). We have also investigated determinants of survival in patients with colorectal cancer.

a. Yuan C, Bao Y, Wu C,..., Stampfer MJ, Giovannucci EL, **Wolpin BM**. Prediagnostic body mass index and pancreatic cancer survival. *J Clin Oncol*. 2013;31(33):4229-34. PMCID: 3821012

b. Wu C, Kraft P, Stolzenberg-Solomon R,..., Fuchs CS, Lin D, **Wolpin BM**. Genome-wide association study of survival in patients with pancreatic adenocarcinoma. *Gut*. 2014;63(1):152-60. PMCID: 3816124

c. Yuan C, Rubinson DA, Qian ZR,..., Kulke MH, Fuchs CS, **Wolpin BM**. Survival among patients with pancreatic cancer and long-standing or recent-onset diabetes mellitus. *J Clin Oncol*. 2015;33(1):29-35. PMCID: 4268250

d. Yuan C, Clish CB, Wu C,..., Vander Heiden MG, Fuchs CS, **Wolpin BM**. Circulating metabolites and survival among patients with pancreatic cancer. *J Natl Cancer Inst.* 2016;108(6). PMID: 26755275

5. Clinical trials in pancreatic cancer: I have extensive experience designing and leading clinical trials for patients with colorectal and pancreatic cancer. These trials range from early-stage safety studies to later stage, randomized studies evaluating treatment efficacy. Furthermore, I am Principal Investigator of a translational trials coalition founded by the Lustgarten Foundation that includes several large academic cancer. Clinical trials run within this Coalition are focused on serial biospecimen collection to understand mechanisms of therapeutic response and resistance. I also serve on committees related to the pancreatic cancer treatment, including the Pancreatic Adenocarcinoma Guidelines Panel of the National Comprehensive Cancer Network (NCCN) and the Gastrointestinal Cancer Committee of the Cancer and Leukemia Group B (CALGB) / ALLIANCE. I am Editor of a *Hematology/Oncology Clinics of North America* issue devoted to PDAC published in August 2015.

a. **Wolpin BM**, Hezel AF, Abrams T,..., Clark JW, Ryan DP, Fuchs CS. Oral mTOR inhibitor everolimus in gemcitabine-refractory metastatic pancreatic cancer. *J Clin Oncol.* 2009;27(2):193-8. PMCID: 2645085

b. **Wolpin BM**, O'Reilly EM, Ko YJ,..., Vincent M, Reyno L, Hidalgo M. Global, multicenter, randomized phase II trial of gemcitabine and gemcitabine plus AGS-1C4D4 in patients with previously untreated, metastatic pancreatic cancer. *Ann Oncol*. 2013;24(7):1792-801. PMCID: 3716216

c.. **Wolpin BM**, Rubinson DA, Wang X,..., Killion L, Mamon HJ, Kimmelman AC. Phase II and pharmacodynamic study of autophagy inhibition using hydroxychloroquine in patients with metastatic pancreatic adenocarcinoma. *The Oncologist*. 2014;19(6):637-8. PMCID: 4041680

d. Coveler AL, Ko AH, Catenacci DV, Von Hoff D, Becerra C, Whiting NC, Yang J, **Wolpin B**. A phase 1 clinical trial of ASG-5ME, a novel drug-antibody conjugate targeting SLC44A4, in patients with advanced pancreatic and gastric cancers. *Invest New Drugs*. 2016. Epub ahead of print. PMID: 26994014

Complete List of Published Work in MyBibliography:

http://www.ncbi.nlm.nih.gov/sites/myncbi/brian.wolpin.1/bibliography/40933695/public/?sort=date&direction=ascending

D. Research Support

Ongoing Research Support:

PRCRP CA130288 (PI: Wolpin) 08/01/14 – 07/31/16
U.S. Department of Defense
Comprehensive Evaluation of Altered Systemic Metabolism and Pancreatic Cancer Risk
This grant leverages a non-targeted metabolomics platform to comprehensively explore thousands of small molecule metabolites in a nested PDAC case-control set from several prospective cohort studies.
Role: Principal Investigator

Research Investigator Grant (PI: Fuchs) 01/01/15 – 12/31/17
Lustgarten Foundation
Obesity-driven PDAC: A Comprehensive Study to Define New Targets for Prevention and Therapy
In this proposal, the combined expertise of clinical researchers and bench scientists from DFCI and MIT study the contribution of obesity to pancreatic cancer development and growth in human studies and mouse models.
Role: Co-Investigator

NIH/NCI 1R21CA191284 (PI: Kraft) 07/01/15 - 06/30/17
Leveraging GxE interaction to understand pancreatic cancer and altered metabolism
The goal of this work is to better understand how germline genetic variants interact with traditional risk factors, such as tobacco, obesity and diabetes mellitus, to predispose individuals to development of pancreatic cancer.
Role: DFCI Site-Principal Investigator

Clinical Science Coalition (PI: Wolpin) 09/01/15 – 08/31/16
Lustgarten Foundation
Translational Science Platform for Evaluation of Targeted Therapies in Patients with Pancreatic Cancer
The goal of this work is to establish a translational science platform across several academic cancer centers to allow for in-depth evaluation of targeted therapies in patients with pancreatic cancer. Studies include serial biopsies of primary and metastatic tumors for whole exome and transcriptome sequencing and generation of living tumor models (patient-derived xenografts and organoids) to study *de novo* and acquired resistance to targeted therapies. Co-investigators include Dr. Levi Garraway of DFCI, Dr. Eileen O'Reilly of Memorial Sloan-Kettering Cancer Center, and Dr. Ronald Evans of the Salk Institute
Role: Principal Investigator

NIH/NCI 1U01CA187508 (PI: Palmer) 09/08/15 - 09/30/19
A prospective investigation of the oral microbiome and pancreatic cancer
A nested case-control study within the Southern Community Cohort Study (SCCS) and Black Women's Health Study (BWHS) will be performed to prospectively investigate the association of the oral microbiome with pancreatic cancer risk. Studies will also be done to examine differences in the oral microbiome by race/ethnicity.
Role: DFCI Site-Principal Investigator

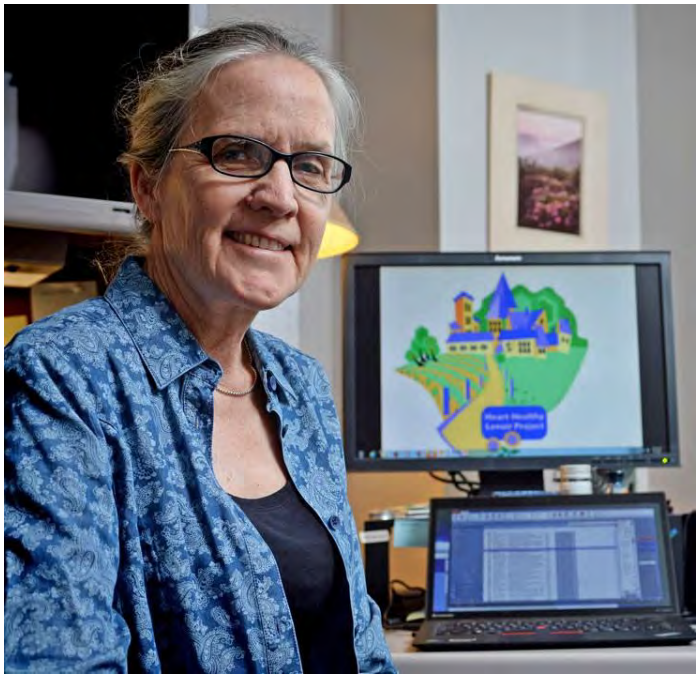
Completed Research Support (selected):

NIH/NCI K07 CA140790 (PI:Wolpin) 09/01/09 – 08/31/14
Cohort Study of Biochemical and Genetic Risk Factors for Pancreatic Cancer
These studies investigate dietary, biochemical, and genetic risk factors for pancreatic cancer related to insulin resistance using germline DNA and prediagnostic plasma collected from five prospective cohort studies.
Role: Principal Investigator

Research Consortium Grant (PIs: Wolpin / Vander Heiden) 07/01/11 – 11/30/15
Lustgarten Foundation
Metabolism and Pancreatic Cancer Pathogenesis: A Multi-institutional Approach to Define Novel Screening Modalities and Treatments for Pancreatic Cancer
This award uses mouse models and patient samples to examine the impact of inherited variations in metabolic enzymes and pathways on progression of pancreatic cancer.
Role: Co-Principal Investigator

Medical Oncology Translational Award (PIs: Wolpin / Bass) 07/01/13 – 06/30/15
Dana-Farber Cancer Institute
Establishing Hypothesis-Driven Genomic Sequencing in Gastrointestinal Cancers
This grant funds the development of a patient-derived xenograft bank and genome sequencing effort in gastro-intestinal cancers.
Role: Co-Principal Investigator.

Alice Ammerman



Alice Ammerman, DrPH

Address: 1700 Martin Luther King Boulevard CB #7426 Chapel Hill, NC 27599
Telephone: (843) 876-1604
Fax: (843) 792-1741
Email: alice_ammerman@unc.edu

Biography

Dr. Ammerman is interested in design and testing of innovative clinical and community-based nutrition and physical activity intervention approaches for chronic disease risk reduction in primarily low income and minority populations. Dr. Ammerman has strong research and practice collaborations across the state addressing childhood obesity and was appointed by the Lieutenant Governor to serve on the Childhood Obesity Study Committee, charged with recommending legislative action around childhood obesity. She is also PI of the Center of Excellence for Training and Research Translation, charged with identification, translation, and

dissemination of evidence-based interventions for obesity and cardiovascular disease control and prevention. More recent research interests focus on school nutrition policy associated with childhood obesity, sustainable agriculture as it relates to improved nutrition, and social entrepreneurship as a sustainable approach to addressing public health concerns.

Honors and Awards

Public Health Systems and Services Research, Academic Researcher Award from the North Carolina Public Health Association
2014, North Carolina Public Health Association

Ned Brooks Award for Public Service
2011, UNC-CH

Excellence in Dietary Guidance Award
2006, American Public Health Association

Greenberg Award
2000, University of North Carolina, Chapel Hill

Delta Omega Honor Society and Special Service Award
1981, University of North Carolina, Chapel Hill

Magna Cum Laude
1976, Duke University

Representative Courses

Co-Teaches NUTR 245: Sustainable, Local Food Systems – Intersection of local foods and public health

NUTR 780: Public Health Entrepreneurship

NUTR 875: Nutrition Policy Seminar

Research Interests

- Aging
- Behavior Science

- Cancer
- Diabetes
- Health Equity
- Health Services and Systems Strengthening
- Heart Disease and Stroke
- Implementation Science
- Nutrition and Physical Activity
- Obesity
- Oral Health
- Public Health Studies (Design, Conduct and Analysis)

Key Publications

Developing an agenda for research about policies to improve access to healthy foods in rural communities: a concept mapping study. A Ammerman, C Byker, W Dean, S Fleischhacker, D Johnson, J Kolodinsky, C Pinard, S Pitts, E Quinn, J Sharkey, M Sitaker (2014). BMC public health, 14(1), 592.

A Comparison of Live Counseling With a Web-Based Lifestyle and Medication Intervention to Reduce Coronary Heart Disease Risk: A Randomized Clinical Trial. A Ammerman, S Bangdiwala, K Donahue, L Draeger, K Evenson, E Finkelstein, Z Gizlice, M Gross, L Johnston, T Keyserling, E Kruger, M Pignone, C Samuel-Hodge, S Sheridan, P Sloane, E Steinbacher, M Vu, B Weiner (2014). JAMA internal medicine.

A systematic approach to evaluating public health training: The obesity prevention in public health course. Alice Ammerman, Rosanne Farris, Cecilia Gonzales, Claire Heiser, Jennifer Leeman, Avia Mainor, Janice Sommers (2014). Journal of Public Health Management and Practice.

Associations Between Neighborhood-Level Factors Related to a Healthful Lifestyle and Dietary Intake, Physical Activity, and Support for Obesity Prevention Polices Among Rural Adults. Alice Ammerman, Kelly Evenson, Beverly Garcia, Ziya Gizlice, Larry Johnston, Thomas Keyserling, Jared McGuirt, Stephanie Pitts, Ann Rafferty, Tosha Smith (2014). Journal of Community Health.

Education

RD, Nutrition, American Dietetic Association, 2007
DrPH, Nutrition, University of North Carolina at Chapel Hill, 1990
MPH, Nutrition, University of North Carolina at Chapel Hill, 1981
BA, Comparative Area Studies in Africa, Anthropology, Duke University, 1976

Joan Bloom

Joan R. Bloom PhD

Address: University of California, Berkeley School of Public Health
50 University Hall #7360 Berkeley, CA 94720
Telephone: (510) 642-4458
Fax: (510) 643-6981
Email: jbloom@berkeley.edu

Biography

Joan Bloom is a Professor of Health Policy and Management at the School of Public Health, University of California, Berkeley. She received her BS from the University of California, Berkeley and a MA in Sociology and Ph.D. in Sociology of Education from Stanford University. Her research interests include: Psycho-social interventions to prevent, encourage early diagnosis, and improve the quality of lives of individuals with chronic disease (e.g. cancer, diabetes, cardiac disease, and chronic mental illness). Current projects include risk notification of men at high risk for prostate and breast cancer; ten year follow-up of young breast cancer survivors, a physical activity intervention to prevent osteoporosis and weight gain in breast cancer survivors, the utilization, cost, and outcomes of capitating mental health services for Medicaid recipients.

Education:

PhD - Sociology of Education, Stanford University
MA - Sociology, Stanford University
BS - University of California, Berkeley

Research Interests:

- Late effects of treatment on cancer survivors
- Effects of Exercise and Diet on Late Effects of Cancer Treatment
- Implementing and sustaining change in health organizations
- Reducing Cancer Disparities in Alameda County

Research Description:

I am interested in the prevention, early detection, and long term effects of chronic disease and its treatment on one's quality of life defined broadly to include the physical, social, psychological and spiritual well-being. I have a special interest in designing and testing interventions to reduce the effects of chronic disease and its treatment. Within this broad area, I am interested in one's response to being at greater than average risk due to one's family history. I have also had an interest in disparities in health outcomes due to age and ethnicity. A second interest has focused on the organizations in which health care is delivered and the effectiveness of new programs that are implemented such as changes in the financing and the delivery of care.

Current Projects:

I am currently completing a ten year follow-up of young women with breast cancer to assess their quality of life compared to their quality of life at five years post-diagnosis and to a cancer-free comparison group. A second project focuses on the effectiveness of an exercise program taking place in YMCAs in the SF Greater Bay Area to reduce the long-term effects of treatment on young women with breast cancer. A third project focuses on outreach, community based participatory research, and training to reduce cancer disparities in Alameda County using religious organizations and community clinics to deliver education, prevention and early detection programs. Other smaller projects fall within these three areas.

Selected Publications:

Fernandes-Taylor S., Bloom JR. Patient Regrets Among Young Breast Cancer Survivors, Psycho-Oncology (in press)

Kaplan C, Napoles A, Hwang S, Bloom JR, Stewart SL, Nickleah D, Karliner L. Selection of treatment among Latina and non-Latina Whites with Ductal Carcinoma in Situ. Journal of Women's Health (in press)

Bloom JR, Wang HH, Kang S, Huang J, Wallace N, Hu T, Capitation of Public Mental Health Services in Colorado: Five-Year Follow-up of System Level Effects, Psychiatric Service (in press)

Bloom JR. The Contributions of Organizational Theory to Health Care., Chapter 18: Research in the Sociology of Organizations, Volume 28, Stanford's Organization Theory Renaissance, 1970-2000, (editors Frank Dobbin and Claudia Bird Schoonhoven), Emerald Press, 2010.

Bloom JR, Stewart SL, D'Onofrio CA, Luce J, Banks PJ. Young Breast Cancer Survivors at Five Year Milestone: Can a short-term, low intensity intervention change behavior? Journal of Cancer Survivorship, 2:190-2004, 2008.

Bloom JR (2007) Improving the health and well-being of cancer survivors, Psycho-Oncology.

Bloom JR, et al. (2006) Effects of a telephone counseling intervention on sisters of young women with breast cancer. Preventive Medicine..

Bloom JR, et al.(2006) Family history, perceived risk and prostate cancer screening among African American Men. Cancer Epidemiology, Biomarkers, and Prevention.

Morris, A. and Bloom, JR (2007) Organizational and individual factors affecting consumer outcomes of care in mental health services, Mental Health Services Research.

Bloom JR, et al. (2002) Mental Health Costs and Access Under Alternative Capitation Systems in Colorado. Health Services Research.

Bloom JR et al (1997) Nursing staffing patterns and hospital efficiency in the US. Social Science and Medicine

Other interests:

- Cancer Prevention Institute of California
- Board of Directors California Dialogue on Cancer
- Member of the Executive Committee State of California
- Breast and Cervical Cancer Advisory Committee
- Psycho-Oncology Editorial Board
- Editorial Board Journal of Cancer Survivorship

Richard Clayton

Department: Health Behavior

Title: Professor Emeritus

Email Address: clayton@uky.edu

Phone: (859) 218-2037

Biography

Dr. Clayton was the first Chair of the Department of Health Behavior and the first Associate Dean for Research in the College of Public Health. Since 1986 he has been the Director of the Center for Prevention Research, the first and only such center funded by the National Institute on Drug Abuse in the first round of funding. From 1996 through 2009 he was Chair of the transdisciplinary Tobacco Etiology Research Network (TERN) funded by the Robert Wood Johnson Foundation. He also served two years as Chair of the transdisciplinary Tobacco Research Network on Disparities (TReND) funded by the National Cancer Institute and the American Legacy Foundation. Both networks involved over 20 senior scientists from disciplines ranging from cells to society and from major research universities around the country.

Dr. Clayton has written 8 books and has published well over 100 articles. He wrote the only required chapter in the first, second and fourth Triennial Reports to Congress on Drug Abuse

and Drug Abuse Research. From 1990-1993 he served on the National Advisory Council for the National Institute on Drug Abuse. In 2005 he received the Presidential Award from the Society for Prevention Research for lifetime contributions to prevention activities and prevention research.

From 1970 until January of 2001 when he accepted the Good Samaritan Foundation Chair position in the UK School of Public Health, he was a Professor in the Department of Sociology at the University of Kentucky. He is the co-developer of the Cooper/Clayton Method to Stop Smoking, a comprehensive behavioral oriented smoking cessation program that utilizes nicotine replacement therapy and group support. Working with the Kentucky Cancer Program and local health departments, Drs. Cooper and Clayton have trained over 1,300 community-based facilitators to deliver the program throughout Kentucky and in a number of other venues as well. Dr. Clayton has been the principal investigator on $28.6 million in extramural grants and a co-investigator on about $16 million in other extramural grants.

In 1984 Dr. Clayton was named by the President as a University Research Professor and, in 1985, he received the Great Teacher Award from the UK Alumni Association. In 2012 he will be working with the National Centre for Youth Mental Health on a nationwide project to reduce self-harm and suicide among youth in Ireland.

Mindie H. Nguyen

Mindie H. Nguyen, MD, MAS, AGAF, FAASLD

Academic email: mindiehn@stanford.edu
Address: 750 Welch Road, 210 Palo Alto, CA 94304
Telephone number 650-498-5691
Fax: 650-498-5692

Biography

Dr. Nguyen is a clinician investigator. She is currently Associate Professor of Medicine and Director for the Hepatology Fellowship in the Division of Gastroenterology and Hepatology and Liver Transplant Program at Stanford University Medical Center and Director for the Hepatology Clerkship for Stanford University School of Medicine. She is also a member of the Stanford Cancer Institute and Bio-X and a Fellow of the American Association for the Study of Liver Diseases.

She has a large and comprehensive practice of general liver as well as liver transplant patients at Stanford University Medical Center and 3 outreach clinics in the San Jose and Los Gatos areas. Her research areas include epidemiology, clinical outcomes, translational studies, and therapeutic clinical trials for chronic hepatitis B, chronic hepatitis C, liver cancer/tumors, other

chronic liver diseases as cause of liver cancer such as nonalcoholic fatty liver disease and liver transplant-related issues. Her research lab includes trainees who are undergraduate students, medical students, graduate students in the Masters' in Epidemiology Program, interns/residents, gastroenterology/hepatology fellows, junior faculty, and visiting scholars. She also serves as Pre-Major Academic Advisor for the undergraduate school.

Her research base includes single-center Stanford-based cohorts, multi-center Bay Area consortium, multi-center US consortia as well as collaborative international cohorts.

She is active in community outreach efforts locally and nationally including service as executive board of director for nonprofit organizations. She serves in the Education and Hepatology Associate Committees for the American Association for the Study of Liver Diseases (AASLD), as member of the Steering Committee for the Hepatobiliary Neoplasia Special Interest Group at AASLD, and has served as member of the Editorial Board for various journals including Gastroenterology.

Dr. Nguyen is also active in Global Health with research collaboration and medical education program and exchanges, with ongoing work in and with several countries in the Asia Pacific region. She is Senior Fellow at the Center for Innovation in Global Health at Stanford University.

She is a Fellow of the American Association for the Study of Liver Diseases and American Gastroenterological Association Fellow. She is also a member of the European Association for the Study of Liver Diseases, the Asia Pacific Association for the Study of Liver Diseases, and the International Liver Cancer Association.

Clinical Focus

- Hepatology and Liver Transplantation
- Liver cancer and tumors
- Chronic hepatitis B and C
- Non-alcoholic fatty liver disease
- Cirrhosis
- End-stage liver disease
- Evaluation of abnormal liver tests
- Community Outreach
- Liver tumors
- Gastroenterology

Academic Appointments

- Associate Professor - Med Center Line, Medicine - Gastroenterology & Hepatology
- Member, Bio-X
- Member, Stanford Cancer Institute

Administrative Appointments

- CIGH Senior Fellow, Center for Innovation in Global Health (CIGH), Stanford University (2015 - Present)
- Steering Committee, HBV Special Interest Group, American Association for the Study of Liver Diseases (AASLD) (2015 - Present)
- Director of Hepatology Fellowship, http://med.stanford.edu/gastrohepfellows/, Stanford University Medical Center (2014 - Present)
- Steering Committee, Hepatobiliary Neoplasia Special Interest Group, American Association for the Study of Liver Diseases (AASLD) (2014 - 2016)
- Director of Hepatology Clerkship, Stanford University School of Medicine (2013 - Present)
- Executive Board of Director, Asian Health Foundation (2013 - Present)
- Liver Section Editor, Journal of Clinical Gastroenterology (2013 - Present)
- Medical Advisory Board, American Liver Foundation (2013 - Present)
- Education Committee, American Association for the Study of Liver Diseases (AASLD) (2013 - 2016)
- Hepatology Associates Committee , MD Liaison, American Association for the Study of Liver Diseases (AASLD) (2013 - 2016)
- Committee Chair, Abstract Review for Chronic Hepatitis B, American Association for the Study of Liver Diseases (AASLD) (2013 - 2013)
- Abstract review member for the Hepatitis B : Epidemiology/Prevention/Control review group, American Association for the Study of Liver Diseases (AASLD) (2011 - 2016)
- Editorial Board, Gastroenterology (2011 - 2014)
- Editorial Board, Digestive Diseases and Sciences (2008 - Present)
- Director of Continuing Medical Education, Pacific Health Foundation (2005 - 2012)
- Director of Clinical Research, Pacific Health Foundation (2004 - Present)
- Training and Workforce Committee, Member, American Association for the Study of Liver Diseases (AASLD) (2002 - 2004)

Honors & Awards

- Senior Fellow at the Center for Innovation in Global Health, Center for Innovation in Global Health, Stanford University, Stanford, CA (2015 Oct)
- Stanford Asian American Faculty Awards, The Asian American Activities Center, Stanford University, Stanford, CA (2015 May)
- 2015 Divisional Teaching Award, Department of Medicine, Stanford University Medical Center, Palo Alto, CA (2015 Dec)
- Pacific Free Clinic Physician Service Award, Cardinal Free Clinics, Stanford University School of Medicine (2013 April)
- The Franklin Edbaugh Advising Award for Faculty, Stanford University School of Medicine (2013 May)
- Chief Fellow in Gastroenterology and Hepatology, Stanford University Medical Center (2002)
- Advanced Hepatology Research Fellow Award, American Association for the Study of Liver Diseases (2001)
- Chief Resident, University of California, San Diego Medical Center (1996)
- Excellence in Teaching Award, University of California, San Diego, School of Medicine (1996)
- Magna Cum Laude, University of California, Irvine (1988)
- Phi Beta Kappa, University of California, Irvine (1985)

Boards, Advisory Committees, Professional Organizations

- See Administrative Appointment Section above, See above (2013 - Present)

Professional Education

- Medical Education: UCSD School of Medicine (1992) CA
- B.S., University of California, Irvine, Biological Sciences (1988)
- M.D., Univ. of California, San Diego, Medicine (1992)
- M.A.S., Univ. of Calif., San Francisco, Masters of Advanced Studies in Clinical Research (2004)
- Internship: UCSD Medical Center (1995) CA
- Residency: UCSD Medical Center (1996) CA
- Fellowship: Stanford University School of Medicine (2002) CA
- Board Certification: Transplant Hepatology, American Board of Internal Medicine (2010)

Jennifer Redmond Knight

Jennifer Redmond Knight DrPH

Department: Health Management and Policy
Title: Research Assistant Professor
Email Address: jennifer.redmond@uky.edu
Phone: (859) 257-3925
Location: 2365 Harrodsburg Rd, Suite A230, Lexington, KY 40504

Biography

Dr. Redmond Knight provides expertise in partnership sustainability, program development and group facilitation, especially related to cancer prevention and control, health promotion and overall chronic disease prevention. She readily builds trust with all types of people and maintains positive relationships with representatives of government, private and non-profit sectors. Dr. Redmond Knight is also known for her natural ability to build enthusiasm and support for some of the most complicated issues in public health today.

She has her BA in Communications from Ouachita Baptist University, Arkadelphia, AR, MPH in Epidemiology and DrPH in Health Services Management both from the University of Kentucky, College of Public Health, Lexington, KY. She has been involved in public health leadership since 2003 when she worked for the Kentucky Cancer Program. Since 2006, Dr. Redmond Knight has been in a leadership role with the Kentucky Cancer Consortium, providing oversight for multi-

functional program activities involving a broad and complex range of public health programs across the continuum of cancer at state and multi-regional levels. Since 2011, she is an Assistant Professor at the University of Kentucky, College of Public Health. In her faculty role, she continues to lead the Kentucky Cancer Consortium, is contracted with the Kentucky Department for Public Health as a facilitator/strategic planner to develop and implement a coordinated Chronic Disease Prevention and Health Promotion Plan for Kentucky and is teaching graduate-level public health leadership course. In September 2012, Dr. Redmond Knight served as a consultant for a Community Transformation Grant in Kentucky where she facilitated regional forums throughout the state. In addition, Dr. Redmond Knight recently served as a consultant for the Cancer Prevention Research Institute of Texas co- facilitating "Future Directions" workgroups that identified areas of success for 2020.

Jamie Studts

Jamie Studts, Ph.D.

Address: 127 Medical Behavioral Science Building
Telephone: (859) 323-0895
Fax: (843) 792-1741
Email: jamie.studts@uky.edu

Position(s): Associate Professor of Behavioral Science
Assistant Director, Cancer Prevention and Control (Markey Cancer Center)
Director, Behavioral and Community-Based Research Shared Resource Facility (Markey Cancer Center)

Affiliation(s): Behavioral Science

Interests / Specialties: Behavioral Oncology

Biography

Dr. Studts enjoyed a productive research, mentoring and service year in 2015. With regard to his research efforts, Dr. Studts serves as the principal investigator of the Kentucky LEADS Collaborative, a multi-level, interdisciplinary project dedicated to developing and evaluating novel provider education, survivorship care, and prevention and early detection interventions to reduce reducing the burden of lung cancer in Kentucky. Dr. Studts also received a grant from the Kentucky Lung Cancer Research Board to continue his research in implementation of lung cancer screening to go along with his NCI-funded research developing a lung cancer screening decision support tool in collaboration with Dr. Margaret Byrne at the University of Miami.

Dr. Studts continued his work with Health Decision Technologies, studying novel point-of-care software package to promote implementation of evidence-based tobacco cessation strategies in obstetrics (NIDA STTR) and dental care settings (NIDCR SBIR). In collaboration with Drs. Joe Valentino and Christina Studts, Dr. Studts co-leads a clinical trial examining the impact of evidence-based tobacco cessation interventions among individuals recently diagnosed with lung or head/neck cancer, funded by a grant from the Kentucky Lung Cancer Research Program and supported by the Kentucky Clinical Trials Network. Dr. Studts has recently been awarded a new grant from NCI in collaboration with colleagues at West Virginia University to study a novel intervention to communicate risk of breast cancer recurrence following treatment for breast cancer. Dr. Studts has continued to work as a co-investigator on an NIEHS funded grant with Dr. Ellen Hahn to conduct a randomized trial of a lung cancer prevention trial involving radon and nicotine testing as well as a NIDA funded grant to Dr. Hannah Knudsen exploring implementation and provider decision making regarding buprenorphine.

Dr. Studts published 2 peer-reviewed academic papers in 2015 and delivered 23 academic presentations, including an invited talk to the Early Detection and Risk Prediction Special Interest Group of the American Society of Preventive Oncology, 2 national presentations, and other talks addressing lung cancer survivorship or implementation of lung cancer screening throughout Kentucky. In the teaching/mentoring domain, Dr. Studts served as the primary mentor for Dr. Jessica Burris' NCI career development grant and co-mentor for Dr. Kate Eddens BIRCWH career development award. Dr. Studts also mentored 3 medical students, 7 graduate students, and served on 9 graduate committees.

With regard to academic and scientific service, Dr. Studts chaired the Quality of Life study section for the Canadian Cancer Society Research Institute, and served as a panel member for the Kentucky Lung Cancer Research Program. He reviewed 15 manuscripts for scientific journals, abstracts for 5 academic conferences, served on the editorial board for the journals Medical Decision Making and Journal of Behavioral Medicine, and was a member of the program committee for the American Society of Preventive Oncology. Dr. Studts continued to serve as the Assistant Director of Cancer Prevention and Control for the Markey Cancer Center, and he expanded his role within the Markey Cancer Center in 2015 by being appointed Director

of the new Behavioral and Community-Based Research Shared Resource Facility. Dr. Studts also serves as a member of the Markey Cancer Center Membership Committee, the Protocol Review and Monitoring Committee, and completed his tenure as a member of the Research Seminar Advisory Committee. Within the Department of Behavioral Science, Dr. Studts served as a member of the Admissions Committee, the Curriculum Committee, and the Undergraduate Course Development Committee. On the state level, Dr. Studts co-leads the Kentucky Lung Cancer Prevention and Early Detection Network of the Kentucky Cancer Consortium and continues to serve on its Survivorship Working Group, the Affordable Care Act and the Radon Action subcommittees. Finally, Dr. Studts serves as a member of the Steering Committee for the UK Center for Health Services Research and a member of the UK Senate Advisory Committee on Faculty Code.

Karen Williams

Karen Patricia Williams, PhD

College: College of Nursing
Department/Division: Center for Women, Children and Youth
Academic Title: Professor
Research Program: Cancer Control
Address: 362 Newton Hall 1585 Neil Ave, Columbus, OH 43210
Telephone: 614-292-1523
Email: williams.5963@osu.edu

Biography

Dr. Williams' research interest is in cancer prevention and control which focuses on cancer disparities. She developed the Kin Keeper Cancer Prevention Intervention to addresses, in part, the continuous cancer burden carried by disenfranchised women of color and women with limited resources. Targeting breast and cervical cancers, the Kin Keeper intervention has been implemented and tested with Black, Latina and Arab women. She is also interested in how families and various culturally-specific networks can be engage in cancer prevention and control.

Publications

Breast Cancer Screening Paved with Good Intentions: Application of the Information-Motivation-Behavioral Skills Model to Racial/Ethnic Minority Women.

Talley CH, Yang L, Williams KP

J Immigr Minor Health in press 02/06/2016

Biographical Sketch

Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form.

NAME PAUL D. BENNY	POSITION TITLE ASSOCIATE PROFESSOR

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training).

INSTITUTION AND LOCATION	DEGREE (IF APPLICABLE)	YEAR(S)	FIELD OF STUDY
Missouri Baptist College, St. Louis, MO	B.S.	1992-1996	Chemistry, Mathematics
University of Missouri-Columbia	Ph.D.	1996-2001	Chemistry (Nuclear)
University of Zurich, Switzerland		2002-2004	Bioinorganic Chemistry

A. POSITIONS AND HONORS

8/2010-Present	Associate Professor, Chemistry Department, Washington State University, Pullman, WA 99164-4630
8/2010-Present	Associate Professor, Department of Pharmaceutical Sciences, Washington State University, Pullman, WA 99164-4630
4/2004-7/2010	Assistant Professor, Chemistry Department, Washington State University, Pullman, WA 99164-4630
12/2005- 7/2010	Assistant Professor, Department of Pharmaceutical Sciences, Washington State University, Pullman, WA 99164-4630
01/2002-3/2004	Postdoctoral Research Assistant (Prof. Roger Alberto, advisor) Inorganic Institute, University of Zürich, Switzerland CH-8057
08/1999-07/2001:	Graduate Research Assistant University of Missouri-Columbia, Columbia, Missouri 65211
06/2000-08/2000:	Teaching Collaborator ACS/DOE Nuclear Chemistry Summer School Brookhaven National Lab, Upton, New York
08/1996-07/1999:	Graduate Teaching Assistant, General Chemistry & Introduction to Radio/Nuclear chemistry University of Missouri-Columbia, Columbia, Missouri 65211
05/1996-08/1996:	Internship in the Nuclear Medicine Division Mallinckrodt Medical Inc., St. Louis, Missouri

HONORS

University of Missouri-Columbia

08/1999-08/2001	Radiochemistry Education Award Program Fellowship
03/2001	MU Research in Creative Activities Award
02/2001	David Troutner Exceptional Work in Radiochemistry Fellowship
03/2000	MU Research in Creative Activities Award
04/1999	Donald K. Anderson Graduate Teaching Award
04/1999	MU Parent's Association Graduate Teaching Award

Missouri Baptist College

04/1996	Chemistry & Math Student of the year

CURRENT ADVISORY POSITIONS

Nuclear Science Advisory Committee (NSAC) for DOE/NSF, Member
American Chemical Society, Nuclear Division, Current Chair
Washington State University Radiation Safety Committee, Current Chair
Washington State University Nuclear Reactor Safe Guards Committee

B. SELECTED PUBLICATIONS (OF 37)

1. Bottorff, Shalina C. ‡, Powell, Ashton S. ∞, Barnes, Charles L., Wherland, Scot Benny, Paul D. * Recovery of rhodium with a novel soft donor ligand using solvent extraction techniques in chloride media. Dalton Trans (2016) *45*, 3264-3267

2. Kasten, Benjamin B. ‡, Ma, Xiaowei, Cheng, Kai, Bu, Lihong, Slocumb, Winston S. ∞, Hayes, Thomas R. ‡, Trabue, Steven, Cheng, Zhen, Benny, Paul D. * Isothiocyanate-Functionalized Bifunctional Chelates and fac-$[M^{I}(CO)_3]^+$ (M = Re, ^{99m}Tc) Complexes for Targeting uPAR in Prostate Cancer Bioconjugate Chemistry (2016), 27(1), 130-142.

3. Hayes, Thomas R. ‡; Powell, Ashton S. ∞; Barnes, Charles L.; Benny, Paul D.* Synthesis and stability of 2+1 complexes of N,N-diethylbenzoylthiourea with $[M^{I}(CO)_3]^+$ (M = Re, ^{99m}Tc) Journal of Coordination Chemistry (2015), 68(19), 3432-3448.

4. Laura H. Davies, Benjamin B. Kasten‡, Paul D. Benny*, Rory L. Arrowsmith, Haobo Ge, Sofia I. Pascu*, Stan W. Botchway, William Clegg, Ross W. Harrington, Lee J. Higham* Re and 99mTc complexes of BodP3 – multi-modality imaging probes Chemical Communications, (2014), 50(98), 15503-15505. cover article

5. Hayes, Thomas R. ‡, Lyon∞, Patrice A., Barnes, Charles, Trabue, Steven, & Benny, Paul. (2015) Influence of Functionalized Pyridine Ligands on the Radio/chemical Behavior of $[M^{I}(CO)_3]^+$ (M = Re, 99mTc) 2+1 Complexes. Inorganic Chemistry, Inorganic Chemistry (2015), 54(4), 1528-1534.

6. Hayes, Thomas R. ‡, Kasten, Benjamin B. ‡, Barnes, Charles L., & Benny, Paul D. (2014). Rhenium and technetium bi- and tricarbonyl complexes in a new strategy for biomolecule incorporation using click chemistry. Dalton Transactions, 43(19), 6998-7001.

7. Paul D. Benny, Thomas R. Hayes‡, Patrice A. Lyon∞ Enhancing chemical properties and stability of $M(CO)_3$ (M = Re, ^{99m}Tc) complexes through ligand donor modifications
Nuclear Medicine and Biology 08/2014; 41(7):615. (Impact Factor 2.41)

8. Zhu, Xiaohua, Li, Jinbo, Hong, Yeongjin, Kimura, Richard H., Ma, Xiaowei, Liu, Hongguang, Qin, Chunxia, Hu, Xiang, Hayes, Thomas R., Benny, Paul, Gambhir, Sanjiv Sam, & Cheng, Zhen. (2014). ^{99m}Tc-Labeled Cystine Knot Peptide Targeting Integrin αvβ6 for Tumor SPECT Imaging. *Molecular Pharmaceutics,* 11(4), 1208-1217. doi: 10.1021/mp400683q

9. Benjamin B. Kasten‡, Xiaowei Ma, Hongguang Liu, Thomas R. Hayes‡, Charles L. Barnes, Shibo Qi, Kai Cheng, Shalina C. Bottorff‡, Winston S. Slocumb∞, Jing Wang, Zhen Cheng‡*, Paul D. Benny* Clickable, hydrophilic ligand for *fac*-$[M^{I}(CO)_3]^+$ (M = Re/^{99m}Tc) applied in an *S*-functionalized α-MSH peptide *Bioconjugate Chemistry,* 25(3), 579-592. doi: 10.1021/bc5000115

10. Shalina C. Bottorff‡, Benjamin B. Kasten‡, Jelena Stojakovic, Adam L. Moore†, Leonard R. MacGillivray, and Paul D. Benny*,Cu-Free 1,3-Dipolar Cycloaddition Click Reactions To Form Isoxazole Linkers in Chelating

Ligands for fac-[$M^{I}(CO)_3]^+$ Centers (M = Re, ^{99m}Tc) *Inorg Chem.* 2014, 53(4):1943-5.

C. OTHER INFORMATION

Curriculum Vitae

Paul Douglas Benny

Personal Data

Birth Date:	22 June 1974
Birth Place:	St. Louis, Missouri
Family:	married, three children
Address:	Washington State University PO Box 644630 Pullman, WA 99164-4630
Phone:	(509) 335-3858
Email:	bennyp@wsu.edu

Education

Ph.D. Radio/Inorganic Chemistry, University of Missouri-Columbia, July 2001
Advisor: Prof. Silvia Jurisson.

B.S. Chemistry & Mathematics, Missouri Baptist College, May 1996.

Professional Experience

8/2010-Present	Associate Professor, Chemistry Department, Washington State University, Pullman, WA 99164-4630
8/2010-Present	Associate Professor, Department of Pharmaceutical Sciences, Washington State University, Pullman, WA 99164-4630
4/2004-7/2010	Assistant Professor, Chemistry Department, Washington State University, Pullman, WA 99164-4630
12/2005- 7/2010	Assistant Professor, Department of Pharmaceutical Sciences, Washington State University, Pullman, WA 99164-4630
01/2002-3/2004	Postdoctoral Research Assistant (Prof. Roger Alberto, advisor) Inorganic Institute University of Zürich, Zürich, Switzerland CH-8057
08/2001- 12/2001:	Assistant Professor (non-tenure track) Natural Science Division (Chemistry) Missouri Baptist College, St. Louis, Missouri 63141
08/1999-07/2001:	Graduate Research Assistant University of Missouri-Columbia, Columbia, Missouri 65211

06/2000-08/2000: Teaching Collaborator
ACS/DOE Nuclear Chemistry Summer School
Brookhaven National Lab, Upton, New York

08/1996-07/1999: Graduate Teaching Assistant, General Chemistry &
Introduction to Radio/Nuclear chemistry
University of Missouri-Columbia, Columbia, Missouri 65211

05/1996-08/1996: Internship in the Nuclear Medicine Division
Mallinckrodt Medical Inc., St. Louis, Missouri

05/1995-08/1995: Summer Research Fellowship
Chemistry Department
Baylor University, Waco, Texas

08/1994-05/1996: Teaching assistant for General & Organic Chemistry,
Chemistry Laboratory Manager
Missouri Baptist College, St. Louis, Missouri

Honors and Awards

University of Missouri-Columbia

08/1999-08/2001	Radiochemistry Education Award Program Fellowship
03/2001	MU Research in Creative Activities Award
02/2001	David Troutner Exceptional Work in Radiochemistry Fellowship
03/2000	MU Research in Creative Activities Award
04/1999	Donald K. Anderson Graduate Teaching Award
04/1999	MU Parent's Association Graduate Teaching Award

Missouri Baptist College

04/1996	Chemistry & Math Student of the year

Professional Societies

1. American Chemical Society, Member
   -member Inorganic Division
   -member Division of Nuclear Chemistry and Technology
   -Vice Chair Elect (2014), Chair Elect (2015), Chair (2016)

2. Radiopharmaceutical Society, member

3. Swiss Chemical Society, Associate

Publications

Research conducted in my laboratory by a
[†]Post Doctoral researcher, [‡]Graduate Student, [∞]Undergraduate Student

38. Carla Daruich de Souza,[1,2] Thomas R. Hayes,[1] Shalina C. Bottorff,[1] Alyssia C. M. Kaczmarczyk,[3] Jason M. Lynam,[3] Paul D. Benny[1,]*Synthesis and evaluation of a carbon monoxide releasing manganese carbonyl complex *J. Chem. Education* (*Submitted 9/2015*) (Impact factor 1.106)

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35. Hayes, Thomas R. [‡]; Powell, Ashton S. [∞]; Barnes, Charles L.; Benny, Paul D.* Synthesis and stability of 2+1 complexes of N,N-diethylbenzoylthiourea with $[M^{I}(CO)_3]^+$ (M = Re, ^{99m}Tc) Journal of Coordination Chemistry (2015), 68(19), 3432-3448. (Impact Factor 2.012)

34. Laura H. Davies, Benjamin B. Kasten[‡], Paul D. Benny*, Rory L. Arrowsmith, Haobo Ge, Sofia I. Pascu*, Stan W. Botchway, William Clegg, Ross W. Harrington, Lee J. Higham* Re and ^{99m}Tc complexes of BodP3 – multi-modality imaging probes
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32. Hayes, Thomas R. [‡], Kasten, Benjamin B. [‡], Barnes, Charles L., & Benny, Paul D. (2014). Rhenium and technetium bi- and tricarbonyl complexes in a new strategy for biomolecule incorporation using click chemistry. Dalton Transactions, 43(19), 6998-7001. (Impact Factor 4.097)

31. Paul D. Benny, Thomas R. Hayes[‡], Patrice A. Lyon[∞] Enhancing chemical properties and stability of $M(CO)_3$ (M = Re, ^{99m}Tc) complexes through ligand donor modifications

Nuclear Medicine and Biology 08/2014; 41(7):615. (Impact Factor 2.41)

30. Zhu, Xiaohua, Li, Jinbo, Hong, Yeongjin, Kimura, Richard H., Ma, Xiaowei, Liu, Hongguang, Qin, Chunxia, Hu, Xiang, Hayes, Thomas R., Benny, Paul, Gambhir, Sanjiv Sam, & Cheng, Zhen. (2014). ^{99m}Tc-Labeled Cystine Knot Peptide Targeting Integrin αvβ6 for Tumor SPECT Imaging. *Molecular Pharmaceutics,* 11(4), 1208-1217. doi: 10.1021/mp400683q (Impact Factor 4.787)

29. Benjamin B. Kasten‡, Xiaowei Ma, Hongguang Liu, Thomas R. Hayes‡, Charles L. Barnes, Shibo Qi, Kai Cheng, Shalina C. Bottorff‡, Winston S. Slocumb∞, Jing Wang, Zhen Cheng‡*, Paul D. Benny* Clickable, hydrophilic ligand for *fac*-$[M^{I}(CO)_3]^+$ (M = Re/^{99m}Tc) applied in an *S*-functionalized α-MSH peptide *Bioconjugate Chemistry,* 25(3), 579-592. doi: 10.1021/bc5000115 (Impact Factor 4.821)

28. Shalina C. Bottorff‡, Benjamin B. Kasten‡, Jelena Stojakovic, Adam L. Moore†, Leonard R. MacGillivray, and Paul D. Benny*,Cu-Free 1,3-Dipolar Cycloaddition Click Reactions To Form Isoxazole Linkers in Chelating Ligands for fac-$[M^{I}(CO)_3]^+$ Centers (M = Re, ^{99m}Tc) *Inorg Chem.* 2014, 53(4):1943-5. (Impact Factor 4.794)

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26. Shalina C. Bottorff‡, Adam L. Moore†, Ariana R. Wemple∞, Dejan-Krešimir Bučar, Leonard R. MacGillivray, Paul D. Benny*pH Controlled Coordination Mode Rearrangements of Huisgen based Multi-dentate ligands with $M(CO)_3^+$ (M= Re, ^{99m}Tc). *Inorg. Chem.* (2013) 2939-2950. (Impact Factor 4.601)

25. Kasten, Benjamin B.‡; Liu, Tiancheng; Nedrow-Byers, Jessie R.; Benny, Paul D.; Berkman, Clifford E. Targeting prostate cancer cells with PSMA inhibitor-guided gold nanoparticles. *Bioorganic & Medicinal Chemistry Letters* (2013), 23(2) 565-568. (Impact Factor 2.539)

24. Jessie R. Nedrow-Byers‡, Adam L. Moore†, Tanushree Ganguly‡, Mark R. Hopkins, Melody D. Fulton, Paul Benny, and Clifford E. Berkman, PSMA-targeted SPECT agents: Mode of Binding effect on in vitro Performance *The Prostate*, (2013) Vol. 73, No.4, 355-362. (Impact Factor 3.377)

23. Tanushree Ganguly‡, Benjamin B. Kasten‡, Thomas R. Hayes‡, Paul D. Benny*, Recent Advances in Re/Tc Radiopharmaceutical Design Utilizing Orthogonal and Metal Template Based Click Reactions. "Technetium: Molecular Composition, Properties and Uses in Medicine" (2012)

22. Han Jiang, Benjamin B. Kasten‡, Hongguang Liu, Shibo Qi, Yang Liu, Mei Tian, Charles L. Barnes, Hong Zhang, Zhen Cheng, Paul D. Benny*, A novel, cysteine-

modified chelation strategy for the incorporation of $M(CO)_3$ (M = Re, ^{99m}Tc) in an α-MSH peptide. *Bioconjugate Chem.* (2012), 23(11), 2300-2312 (Impact Factor 4.930)

21. Jessie Nedrow-Byers[‡], Mohamed Jabbes, Cayla Jewett[∞], Tanushree Gangly[‡], Haiyang He[†], Tiancheng Liu, Paul Benny, Jeffrey N. Bryan, and Clifford E. Berkman, Phosphoramidate-Based Prostate-Specific Membrane Antigen-Targeted SPECT Agent, *The Prostate*, (2012) Vol. 72, 904-912. (Impact Factor 3.377)

20. Tanushree Ganguly[‡], Benjamin Kasten[‡], Dejan-Krešimir Bučar, Leonard R. MacGillivray, Paul D. Benny*, The hydrazide/hydrazone click reaction as a biomolecule labeling strategy for $M(CO)_3$ (M = Re, ^{99m}Tc) radiopharmaceuticals. *Chem. Comm.*, (2011), 47, 12846-12848. (Impact Factor 5.787)

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17. Paul D. Benny*, Adam L. Moore[†] Recent Advances in the Probe Development of Technetium-99m Molecular Imaging Agents, *Current Organic Synthesis,* (2011) Vol. 8, Issue 4, 566-583. (Impact Factor 3.952)

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13. He, Haiyang[†]; Morley, Jennifer E.[∞]; Twamley, Brendan; Groeneman, Ryan H.; MacGillivray, Leonard R.; Benny, Paul D.[*] Synthesis and Characterization of the Coordination Interactions of S-Methylpyridyl-Cysteine Ligands with $M(CO)_3^+$

(M=^{99m}Tc, Re) *Inorganic Chemistry* (2009), *48* (22), pp 10625–10634. (Impact Factor 4.325)

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11. He, Haiyang[†]; Morley, Jennifer E.[∞]; Silva-Lopez, Elsa[‡]; Bottenus, Brienne[∞]; Montajano, Maribel[∞]; Fugate, Glenn A. [†]; Twamley, Brendan; Benny, Paul D.* Synthesis of Flutamide Linked $M(CO)_3^+$ Compounds for Androgen Receptor Targeting in Prostate Cancer Imaging, *Bioconjugate Chemistry* (2009), 20(1), 78-86. (Impact Factor 5.002)

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9. Benny, Paul D.*; Fugate, Glenn A.[†]; Barden, Adam O.[‡]; Morley, Jennifer E.[∞]; Silva-Lopez, Elsa[‡]; Twamley, Brendan. Metal Assisted *In situ* Formation of a Tridentate Acac Ligand for Complexation of *fac*-$Re(CO)_3^+$ for Radiopharmaceutical Applications *Inorganic Chemistry* (2008), 47(7), 2240-2242. (Impact Factor 1.94)

8. van Staveren, Dave R.; Benny, Paul D.; Waibel, Robert; Kurz, Philipp; Pak, Jae-Kyoung; Alberto, Roger.* S-functionalized cysteine: Powerful ligands for the labelling of bioactive molecules with triaquatricarbonyltechnetium-99m(1+) ([$^{99m}Tc(OH_2)_3(CO)_3$]+). *Helvetica Chimica Acta* (2005), 88(3), 447-460.

7. Benny, Paul D.; Green, Jenny L.; Engelbrecht, Hendrik P.; Barnes, Charles L.; Jurisson, Silvia S.* Reactivity of Rhenium(V) Oxo Schiff Base Complexes with Phosphine Ligands: Rearrangement and Reduction Reactions. *Inorganic Chemistry* (2005), 44(7), 2381-2390.

6. Green, Jenny L.; Benny, Paul D.; Engelbrecht, Hendrik P.; Barnes, Charles L.; Jurisson, Silvia S.* Substitution and intramolecular rearrangement of *trans*-[ReO(X)($acac_2$en/pn)]0/+ (X = OH_2 or Cl^-) to yield asymmetric *cis*-[ReO(Y)($acac_2$en/pn)] complexes with cyanide and thiocyanate. *Synthesis and Reactivity in Inorganic, Metal-Organic, and Nano-Metal Chemistry* (2005), 35(1), 53-59.

5. Alberto, Roger*; Pak, Jae Kyong; van Staveren, Dave; Mundwiler, Stefan; Benny, Paul. Mono-, Bi-, or tridentate ligands? The labeling of peptides with ^{99m}Tc-carbonyls. *Biopolymers* (2004), 76(4), 324-333.

4. Benny, Paul D; Barnes, Charles L; Piekarski, Pamela M; Lydon, John D; Jurisson, Silvia S.* Synthesis and characterization of novel rhenium(V) tetradentate N_2O_2 Schiff base monomer and dimer complexes. *Inorganic Chemistry* (2003), 42(20), 6519-27.

3. Pak, J.K.; Benny, P.; Spingler, B.; Ortner, K.; Alberto, R.* N^{ε} Functionalization of Metal and Organic Protected L-Histidine for a Highly Efficient, Direct Labeling of Biomolecules with $[Tc(OH_2)_3(CO)_3]^+$. *Chem. Eur. J.* (2003), 2053-2061.

2. Pak, J.K.; Benny, P.; Alberto, R.* Tc(I)/Re(I)-Tricarbonyl Complexes with N^t-functionalized Histidine Ligands. Alberto, R.; *Technetium, Rhenium, and Other Metals in Chemistry and Nuclear Medicine.* (2002), 151-154.

1. Benny, P.; Pak, J.K.; Alberto, R.* Rhenium(I)Tricarbonyl Histidine Modified Complexes and Studies of the Demetallization of the Rhenium Complex.. *Technetium, Rhenium, and Other Metals in Chemistry and Nuclear Medicine*. (2002), 159-161.

Presentations

Research conducted in my laboratory by a
[†]Post Doctoral researcher, [‡]Graduate Student, [∞]Undergraduate Student

53. Hayes, Thomas R.; Slocumb, Winston S. [∞]; Lyon, Patrice A. [∞]; Barnes, Charles L.; Benny, Paul D. Effect of charge and nitrogen donors on the stability and labeling of *fac*-[^{99m}TcI(CO)3]+ 2 + 1 complexes. Abstracts of Papers, 250th ACS National Meeting & Exposition, Boston, MA, United States, August 16-20, 2015 (2015), FLUO-12.

52. Benny, Paul D.; Bottorff, Shalina C. [‡]; Powell, Ashton S. [∞]; Hayes, Thomas R. [‡] Recovery of precious metals from spent nuclear waste. Abstracts of Papers, 250th ACS National Meeting & Exposition, Boston, MA, United States, August 16-20, 2015 (2015), I+EC-41.

51. Hayes, Thomas R. [‡]; Lyon, Patrice A. [∞]; Barnes, Charles L.; Trabue, Steven L.; Benny, Paul D. Development of new ligands for $[M^I(CO)_3]^+$ (M= Re, ^{99m}Tc) complexes with enhanced chemical properties and stability. Abstracts of Papers, 249th ACS National Meeting & Exposition, Denver, CO, United States, March 22-26, 2015 (2015), INOR-885.

50. B. B. Kasten[1‡], X. Ma[2], K. Cheng[2], L. Bu[2], Z. Cheng[2], P. D. Benny[1] Isothiocyanate-functionalized bifunctional chelates for ^{99m}Tc and Re complexes for uPAR targeting in prostate cancer (6/2015) International Symposia Radiopharmaceutical Sciences meeting Columbia, MO.

49. Thomas R. Hayes[‡], Patrice. Lyon[∞], Charles Barnes, Paul D. Benny. "Development of Ring Substituted Pyridine Chelates for *fac*-$[M^I(CO)_3]^+$ (M = Re, ^{99m}Tc) Based Radiopharmaceuticals." (6/2015) International Symposia Radiopharmaceutical Sciences meeting Columbia, MO.

48. Paul D. Benny, Thomas R. Hayes‡, Patrice A. Lyon∞, Enhancing chemical properties and stability of $M(CO)_3$ (M= Re, ^{99m}Tc) complexes through ligand donor modifications, Terachem: Rhenium, Technetium and Other Metals in Nuclear Medicine, Bressonone, Italy, 9/10-9/13 2014

47. Thomas R. Hayes‡, Patrice. Lyon∞, Charles Barnes, Paul D. Benny. "Influence of pyridine basicity on complexation and stability of fac-$[M^I(CO)_3]^+$ (M = Re, ^{99m}Tc) complexes." Missoula, MT. 6/22-6/25 2014 ACS Northwest Regional Meeting.

46. Paul D. Benny, Shalina C. Bottorff‡, Ashton S. Powell∞ New ligand designs for recovery of precious metals from spent nuclear fuel Abstracts of Papers, 248th ACS National Meeting & Exposition, San Francisco, CA, United States, August 10-14, (2014), NUCL

45. Shalina C. Bottorff‡, Benjamin B. Kasten‡, Jelena Stojakovic, Adam L. Moore†, Leonard R. MacGillivray, and Paul D. Benny* Isoxazole click reactions as linkers for *fac*-$[M^ICO)_3]^+$ (M = Re, 99mTc) complexes Pugest Sound Women Chemists Retreat May 31, 2014 Vancouver, British Columbia, Canada

44. Jessie Nedrow-Byers[1], Tanushree Ganguly‡, Adam Moore[1], Paul Benny[1], Henry Vanbrocklin[2], Ella Jones[2] and Clifford Berkman[1]. The effects of mode of binding on clickable PSMA-targeted imaging agents. J. Nucl. Med. 2012; 53 (Supplement 1):1539

43. Tanushree Ganguly‡, Jessie Nedrow-Byers[1], Paul Benny[1] and Clifford Berkman[1] Targeting prostate-specific membrane antigen with a phosphoramidate-based SPECT agent. J. Nucl. Med. 2012; 53 (Supplement 1):1695

42. Benny, Paul D. Developing click reactions for facile coupling of Re/^{99m}Tc$(CO)_3$ to biomolecules. Abstracts of Papers, 243rd ACS National Meeting & Exposition, San Diego, CA, United States, March 25-March 29, 2012 (2012), NUCL-29.

41. Johnston, Kimberly M.; Mezyk, Stephen P.; Wemple, Ariana∞; Jewett, Cayla M.∞; Benny, Paul D., Investigation of the redox stability of radiopharmaceutical $M(CO)_3$ (M = Re, Tc-99m) amino acid complexes in physiological aqueous solution, 241st ACS National Meeting & Exposition, Anaheim, CA, United States, March 27-31, 2011.

40. P. D. Benny* Successes, Failures and Current Developments in the Development of ^{99m}Tc Androgen receptor targeting Agents For Prostate Cancer Imaging, DOD Innovative Minds in Prostate Cancer Today conference, Orlando, FL, March 9-12, 2011.

39. Johnston, K. M.; Mezyk, S. P.; Wemple, A.∞; Jewett, C. M.∞; Benny, P. D. Investigation of the radiation effects and redox stability of $M(CO)_3$ (M = Re, Tc-99m) amino acid complexes in aqueous solution Pacifichem 2010, International Chemical Congress of Pacific Basin Societies, Honolulu, HI, United States, December 15-20, 2010 (2010), HEALTH-226.

38. Nedrow-Byers, J.; Berkman, C. E.; Benny, P.; Blecha, J. E.; Pharm, D.; Jones, E. F.; Van Brocklin, H. F.; Jabbes, M.; Bryan, J. N. Development of PSMA-targeted PET and SPECT imaging agents for prostate cancer. Pacifichem 2010, International Chemical Congress of Pacific Basin Societies, Honolulu, HI, United States, December 15-20, 2010 (2010), BIOL-45.

37. Tanushree Ganguly‡, P. D. Benny* Click chemistry design and molecular imaging applications in targeting prostate cancer with Tc-99m Pacific Chem Dec 15th, 2010.

36. P. D. Benny* Development of Organometallic Molecular Imaging Agents for Targeting Prostate Cancer, Iowa University, Iowa City, IA October 28, 2010.

35. P. D. Benny* Development of Organometallic Molecular Imaging Agents for Targeting Prostate Cancer, Grinnell College, Grinell, IA October 23, 2010.

34. Johnstron, Kimberly M. ∞; Mezyk, Stephen; Wemple, Ariana∞; Jewett, Cayla M. ∞; Benny, Paul D.. Investigation of the radiation effects and redox stability of $M(CO)_3$ (M = Re, Tc-99m) amino acid complexes in aqueous solution. Abstracts of Papers, 240th ACS National Meeting, Boston, MA, United States, August 22-26, 2010, NUCL-58.

33. Benny, Paul D.*; Byers, Jessie; Jabbes, Mohamed; Berkman, Clifford; Bryan, Jeffrey N. Targeting the prostate specific membrane antigen in prostate cancer with Tc-99m phosphoramidate inhibitors. Abstracts of Papers, 240th ACS National Meeting, Boston, MA, United States, August 22-26, 2010, NUCL-149.

32. Nedrow-Byers, Jessie; Benny, Paul; Berkman, Clifford E.; Bryan, Jeffrey N. The development of PSMA-targeted SPECT imaging agents for prostate cancer. Abstracts, Joint 65th Northwest and 22nd Rocky Mountain Regional Meeting of the American Chemical Society, Pullman, WA, United States, June 20-23, 2010, NWRM-101.

30. Ganguly, Tanushree; Fugate, Glenn A.; Benny, Paul D.. Investigation of Novel Acetylacetone with Imidazole/Histamine Complexes with fac-$M(OH_2)_3(CO)_3^+$ (M = Re, 99mTc). Abstracts, Joint 65th Northwest and 22nd Rocky Mountain Regional Meeting of the American Chemical Society, Pullman, WA, United States, June 20-23 2010, NWRM-40.

29. Wemple, Ariana R.; Benny, Paul D.; Moore, Adam L. Click labeling of tricarbonyl metal cores (Re and ^{99m}Tc) for prostate cancer imaging. Abstracts, Joint 65th Northwest and 22nd Rocky Mountain Regional Meeting of the American Chemical Society, Pullman, WA, United States, June 20-23 2010, NWRM-74.

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27. P. D. Benny* The Radiochemistry Program at Washington State University,

Seattle Pacific University, Seattle, WA, April 14, 2010.

26. P. D. Benny* Targeting PSMA with ^{99m}Tc inhibitor complexes, Radiochemistry and Radionuclide Imaging Instrumentation Program Investigators Workshop, Department of Energy January 5-6, 2010.

25. Clark, Sue B.; Nash, Kenneth L.; Benny, Paul; Clark, Aurora; Wall, Nathalie A.; Yoo, Choong-shik; Wall, Donald E. Renaissance of and sustaining an academic radiochemistry program in a chemistry department: The experience at Washington State University. Abstracts of Papers, 238th ACS National Meeting, Washington, DC, United States, August 16-20, 2009, NUCL-210.

24. P. D. Benny* Novel Applications of Organometallic complexes in Prostate Cancer Targeting, Northeastern University, Boston, MA, November 4, 2009.

23. P. D. Benny* Imaging the androgen receptor in prostate cancer with organometallic Tc-99m compounds, 238th American Chemical Society meeting, Washington DC, August 15-20, 2009.

22. P. D. Benny*, H. He[†], J. Morley[∞]. Functionalized Cysteine Derivatives for Labeling $Tc(CO)_3$, *Society of Radiopharmaceutical Symposia,* Edmonton, Canada, July 2009.

21. Byers, Jessie[‡]; Berkman, Clifford; Benny, Paul*; Porter, Tom. The development of a PSMA targeted imaging agent for prostate cancer. 237th ACS National Meeting, Salt Lake City, UT, United States, March 22-26, 2009.

20. Filling the "Isotope Specialist" Pipeline: The Washington State University Approach, Kenneth L. Nash, Sue B. Clark, Paul Benny*, Aurora Clark, Donald Wall, Nathalie Wall, and James Elliston. American Nuclear Society, Anaheim, CA June 2008.

19. Targeting Prostate Cancer through the Androgen Receptor with Organometallic Tc-99m Flutamide Derivatives. Benny, Paul*; Silva-Lopez, Elsa[‡]; Bottenus, Brienne[∞]; Montejano, Maribel[∞]: Prostate Cancer Research Program Meeting, Atlanta, GA Sep. 7-10, 2007.

18. Paul Benny*, Eileen Morley[∞], Elsa Silva-Lopez[‡], Daniel Vanderbilt[∞]. "Targeting Prostate Cancer through the Androgen Receptor with Organometallic Tc-99m Flutamide Derivatives" Washington State University, Fourth Annual College of Sciences Undergraduate Research Poster Competition, March, 2007.

17. Targeting Prostate Cancer through the Androgen Receptor with Organometallic Tc-99m Flutamide Derivatives. Benny, Paul*; Silva-Lopez, Elsa[‡]; Bottenus, Brienne[∞]; Montejano, Maribel[∞]: 11TH Prouts Neck Meeting on Prostate Cancer NIH/NCI Meeting, Prouts Neck, Maine, Nov. 2-5, 2006.

16. REAP Investments in the radiochemistry program at Washington State University. Benny, Paul*; Clark, Aurora; Clark, Sue; Nash, Kenneth L. Abstracts of Papers, 232nd ACS National Meeting, San Francisco, CA, United States, Sept. 10-14, 2006.

15. *In situ* formation of tridentate ligands in aqueous media from 2, 4-pentanedione to form imine complexes around $[M(CO)_3(OH_2)_3]^+$ (M=Re, ^{99m}Tc) centers. Fugate, Glenn A.†; Bottenus, Brienne N.$^{\infty}$; Benny, Paul*. Abstracts of Papers, 232nd ACS National Meeting, San Francisco, CA, United States, Sept. 10-14, 2006.

14. S-functionalized cysteine ligands for complexation with $M(CO)_3^+$ M=Re, ^{99m}Tc for diagnostic applications. Bottenus, Brienne N.$^{\infty}$; Fugate, Glenn A.†; Benny, Paul*. Actinides Separations, Conference Pacific Northwest National Lab, June, 2006.

13. In situ formation of tridentate ligands in aqueous media from 2, 4-pentanedione to form imine complexes around $[M(CO)_3(OH_2)_3]^+$ (M=Re, ^{99m}Tc) centers. Fugate, Glenn A.†; Bottenus, Brienne N.$^{\infty}$; Benny, Paul*. Actinides Separations, Conference Pacific Northwest National Lab, June, 2006.

12. S-functionalized cysteine ligands for complexation with $M(CO)_3^+$ M=Re, ^{99m}Tc for diagnostic applications. Bottenus, Brienne N.$^{\infty}$; Fugate, Glenn A.†; Benny, Paul*. Abstracts of Papers, 231st ACS National Meeting, Atlanta, GA, United States, March 26-30, 2006.

11. Radiochemical separations in nuclear medicine: Where are we now and where we can go? Benny, Paul*. 229th ACS National Meeting, San Diego, CA, USA, March 2005.

10. Synthesis of novel amino acid derivatized ligands for complexation of *fac*-$M(CO)_3^+$, M= ^{99m}Tc, Re. Benny, Paul*; Pak, Jae Kyoung; Spingler, Bernhard; Kurz, Phillip; Alberto, Roger. 228th ACS National Meeting, Philadelphia, PA, United States, August 22-26, 2004.

9. Chemistry and radiochemistry of rhenium and technetium phosphine complexes. Green, Jenny L.; Benny, Paul*; Jurisson, Silvia S.; Engelbrecht, Hendrik; Barnes, Charles L. 228th ACS National Meeting, Philadelphia, PA, United States, August 22-26, 2004.

8. Rhenium as a Protecting Group: Modification of the $^{\varepsilon}$N of *fac*-$Re(CO)_3$(Histidine) and Subsequent Labeling with *fac*-$^{99m}Tc(CO)_3^+$ Benny, P.*; Pak, J.K.; Alberto, R. Presented at the 15th annual FE Chem Conference, Zurich, Switzerland, August 10-15, 2003.

7. Rhenium(I)Tricarbonyl Histidine Modified Complexes and Studies of the Demetallization of the Rhenium Complex. Benny, P.*; Pak, J.K.; Alberto, R. Presented at the sixth international symposium on technetium in chemistry and nuclear medicine in Bressanone, Italy, September 4-7, 2002.

6. Novel Rhenium (V) N_2O_2 Schiff Base Monomer Complexes. Paul D. Benny*, Charles Barnes, Silvia Jurisson. Presented at the Pacifichem international meeting of the American Chemical Society in Honolulu, Hawaii, December 17-22, 2001.

5. Unraveling the Mysteries of Rhenium (V) Oxo Schiff Base Complexes. Benny, P.* Presented at the Dynamite Seminar, Chemistry Department, University of Missouri-Columbia, Feb 2000.

4. Synthesis and Characterization of Novel Rhenium(V) Schiff Base Complexes. Benny, P.*; Barnes, C.; Jurisson, S. Presented at the Missouri Inorganic Day, University of Missouri-St. Louis, May 1999.

3. Technetium and Rhenium (V) Schiff Base Complexes. Benny, P.*; Jurisson, S. Presented at the Dynamite Seminar, University of Missouri-Columbia, April 1998.

2. Rhenium (III) & (V) Schiff Base Complexes. Benny, P.*; Lydon, J.; Barnes, C.; Jurisson, S. Presented at the 215th national meeting of the American Chemical Society in Dallas, Texas, March 29-April 2 1998.

1. Rhenium (V) Schiff Base Complexes. Benny, P.*; Lydon, J.; Barnes, C.; Jurisson, S. Presented at Missouri Inorganic Day at University of Missouri-Columbia, May 1998.

Invited Lectures

9/2014	School of Chemistry, Newcastle University, Newcastle, England
9/2014	Department of Chemistry, University of York, England
6/2012	Guest lecture, DOE Nuclear Chemistry Summer School San Jose State University, San Jose, CA
3/9-12/2011	DOD IMPACT Prostate cancer conference, Orlando, FL
6/2011	Guest lecture, DOE Nuclear Chemistry Summer School San Jose State University, San Jose, CA
10/28/2010	Iowa University, Iowa City, IA
10/23/2010	Grinnell College, Grinnell, IA
4/14/2010	Seattle Pacific University, Seattle, WA
11/4/2009	Northeastern University, Chemistry Colloquium, Boston, MA
8/19/2009	American Chemical Society, Molecular Imaging Section (Inorg/DNCT), Washington DC
4/2/2009	School of Molecular Biosciences Colloquium, Washington State University

3/17/2009	Missouri Baptist University, Student Seminar, Careers in Prostate Cancer Molecular Imaging
3/16/2009	St. Louis University, Chemistry/Biochemistry Seminar,
3/13/2009	University of Missouri-Columbia, Chemistry Colloquium,
12/9/2008	Univ. of Idaho-Moscow, Chemistry Colloquium,
9/9/2008	Stanford University, Molecular Imaging Group
9/10/2008	Probe development Meeting, Univ. of California- San Francisco
3/26/ 2008	Radiochemistry at Washington State University. Paul Benny. The Cure Start Here, Symposium for Medical Isotope Applications, Kennewick, WA.
4/18/2008	Future Directions in Prostate Cancer Imaging, Paul Benny. The Idaho Society of Radiologic Technologists, Lewiston, ID.
4/2008, 4/2007 4/2006, 4/2005	Pharmaceutical Applications of Nuclear Medicine. Benny, Paul PharS 534 course, Washington State University, Pullman, WA
3/12/2006	Organometallics in the Design of Radiopharmaceuticals for Molecular Imaging Applications. Department of Pharmaceutical Sciences *s*eminar, Washington State University, Pullman, WA
3/13-17/2005	Radiochemical separations in nuclear medicine: Where are we now and where we can go? Benny, Paul. 229th ACS National Meeting, San Diego, CA, United States,
07/2002, 07/2003 07/2004, 07/2005	Guest Lecturer Nuclear Medicine Symposium ACS/DOE Nuclear Chemistry Summer School Brookhaven National Lab, Upton, New York

Peer Journal Reviewer for the following Peer Reviewed Publications

Analytical Methods	(1)
Applied Radiation Isotopes	(1)
Bioconjugate Chemistry	(11)
Bioorganic and Medicinal Chemistry Letters	(2)
Chemistry Communications	(1)
Chem Review	(1)
Dalton Transactions	(3)

European Journal of Inorganic Chemistry	(2)
European Journal of Nuclear Medicine	(1)
European Journal of Nuclear Medicine and Molecular Imaging	(7)
Inorganic Chemistry	(14)
Inorganic Chimica Acta	(3)
Inorganic Chemistry Communications	(3)
Journal of Coordination Chemistry	(3)
Journal of Pharmacy and Pharmacology	(1)
Journal of Labelled Compounds and Radiopharmaceuticals	(1)
Journal of Scientific and Industrial Research	(7)
Macromolecules	(1)
Molecular Pharmaceuticals	(3)
Molbank	(1)
Radiochimica Acta	(6)
Radiolabeled Compounds	(2)

Reviewer for the Following Granting Organizations

DOD Prostate Cancer Idea Development	11/2015
DOE Integrated Nuclear Medicine Research and Training Projects of Excellence	5/2012
DOD Prostate Cancer Hypothesis award	07/2011,8/2012, 2013, 2014
DOE Integrated Radiochemistry and Instrumentation	06/2010
NSF Chemistry of Life Processes (CLP) Program in the Division of Chemistry	03/2010
DOE Integrated Radiochemistry and Instrumentation	06/2009
DOE Integrated Radiochemistry Research Projects of Excellence	05/2009
American Cancer Society-Internal WSU grant panel	11/2008, 11/2009, 11/2010, 11/2011
DOD Prostate Cancer Research Program	
Idea Award, Predoctoral, Post Doc Training Program	10/2011, 07/2010,
Molecular Imaging and therapeutic sections	07/2009, 09/2008
DOD Breast Cancer Research Program	
Molecular Imaging section	04/2007

DOD Prostate Cancer Research Program (PCRP)
Molecular Imaging section 06/2006

Reviewer for the following Awards

WSU College of Science Undergraduate Poster Session 2005-2010 (yearly)

WSU College of Pharmacy and Toxicology Poster Session 2005-2010 (yearly)

Organizer for the following Symposia/Events

Conference presider at the International Symposia Radiopharmaceutical Sciences meeting Columbia, MO. 6/2015

Topics in Nuclear Medicine, Division of Nuclear Chemistry and Technology, National Meeting of the American Chemical Society, San Diego, CA 3/2012

Inorganic Section, Regional American Chemical Society, Pullman, WA 6/21-26/2010

Graduate Student Symposia, Division of Nuclear Chemistry And Technology, National Meeting of the American Chemical Society, Boston, MA 8/2010

Organizer of General Chemistry 106 visitation to the WSU reactor 4/2007-current

Service at WSU

Analytical, Environmental, and Radiochemistry Departmental Advisory Committee Representative 11/2012-8/2014

Radiation Safety Committee Chairman 8/2013-current

Radiation Safety Committee Member 9/2009-current

WSU Reactor Safe Guards Committee Member 9/2010-current

Graduate Recruiting Committee Member 9/2006-current

General Chemistry Oversight Committee Member 1/2009-current

Current Funded Projects

OGRD# 116767-001
Nuclear Energy University Program 11/1/11-9/28/2015
Department of Energy $500,000
00014002
Role on the Project: (co-PI) 0.500 calendar month (4.16%)
Contact: Elise Miller, elise.miller@inl.gov
Rapid Computer Aided Ligand Design and Screening of Precious Metal Extractants from TRUEX Raffinate with Experimental Validation
The proposal combines the development of novel ligands for complexing platinum group metals combined with computational analysis to predicted better design systems to enhance extraction capabilities in the nuclear fuel reprocessing stream.
Overlap: none

Department of Defense 8/17/2015-8/16/2016
CDMRP $114,000
Role on the Project: (PI) 1.00 calendar month (8.33%)
Multivalent targeted theranostic liposomes for chemo-resistant aggressive CaP"
The proposal develops multi-targeted liposomes for synergisitic delivery of diagnostics and therapeutics for enhanced hetorgenous tumor detection therapeutic efficacy.

Pending Research Support

OGRD# 124873-001
NNSA/Department of Energy
Grants.gov ID grant11770621
$798,558 5/1/15-4/30/18
Role on the Project: (PI) 1.0 calendar (8.33%)
Contact: Delmeria Pacheco, Delmeria.Pacheco@nnsa.doe.gov
Tunable magnetic nanoparticles for separation and preconcentration of technetium for trace detection
The goal of the proposal is develop a magnetic nanoparticle platform to selectively bind ^{99}Tc for removal from solution. The specific aims of the proposal focus on the development of three platforms for removing Tc in different oxidation states, and the development of a continuous flow magnetic extractor.

OGRD # 124034-002
Department of Defense
Grants.gov No. GRANT11741040
$375,000 (direct) 5/1/2014-4/30/2017
Role on the Project: (co-PI) 1.0 calendar (8.33%)

No program manager listed

Hetero bivalent targeting of aggressive CaP for improved diagnostic assessment in preclinical models
The proposal utilizes a hetro bivalent platform to target aggressive prostate cancer cells that express either PSMA or GRP receptors for diagnostic imaging with ^{99m}Tc.

OGRD# 122360-002
Grayson-Jockey Club Research Foundation
No ID number assigned
$48,709 (direct) 4/1/15-3/31/17
Role on the Project: (co-PI) 0.25 calendar month (2%)
Contact: Resia Ayres, rayres@tjcis.com
Title: *Use of a Novel Bisphosphonate in the Horse Bone Scan*
The overall goal of the proposal focuses on the development of an improved bone agent to reduce radiation dose to animal care workers conducting routine bone scans. The specific aims to develop a bisphonate analog with a functionalized ligand for complexing $^{99m}Tc(CO)_3$ for enhanced binding to bone matrix and to examine in vitro and in vivo on rats and horse diagnostic models.

Previously Funded Projects

2374880 (PI: Berkman) 12/1/08- 11/30/11
LSDF 08-01: $679,965.00
Role on the Project: (Co-PI) 2.00 calendar
Chemoaffinity Agents for the Detection of Prostate Cancer

DE-PS02-08ER08-11 10/1/08 – 9/30/11
DOE $622,266
Role on the Project: (PI) 1.00 calendar
Development of Prostate Specific Membrane Antigen (PSMA) Inhibitors Coupled to $^{99m}Tc(CO)3^{+}$ with Enhanced Specific Activity for SPECT Imaging

Department of Defense 10/01/2005-9/30/2009
Prostate Cancer New Investigator Award $330,000
Diagnostic and Therapeutic Radiopharmaceutical Agents for Selective Discrimination of Prostate Cancer
Role: PI

Department of Energy 7/01/2005-6/30/2008
Research and Education Award Program III $275,000
Instrumental development of the radiochemistry facilities at Washington State University
Role: PI

Courses Taught

Credit Hours

Washington State University

Chemistry 106, General Chemistry II#	4
Chemistry 220, Quantitative Analysis	2
Chemistry 398, Undergraduate Chem. Majors course	1
Chemistry 501, Advanced Inorganic Chemistry*	3
Chemistry 410, Advanced Synthesis laboratory*	3
Chemistry 422/522, Radio and Nuclear Chemistry Lab*	2
Chemistry 520, Analytical Chemistry	3
Chemistry 529, Radiopharmaceutical Chemistry#	2
Chemistry 590, Introduction to Research*	1
Chemistry 592, AER Seminar	1
PharmS 534, Pharmaceutical Biotechnology#	3

University of Missouri-Columbia

Chemistry 31, General Chemistry I Lab	1
Chemistry 361, Introduction to Radio & Nuclear Chemistry Lab	1

Missouri Baptist College

Chemistry 135, General Chemistry I	4
Chemistry 135L, General Chemistry I Lab	1
Chemistry 394, Environmental Chemistry#	3
Chemistry 394L, Environmental Chemistry Lab#	1
Chemistry 413, Physical Chemistry I	3

*Indicates a major contribution in redesign of the course
#New course offering or new contribution to the course

References

1) **Prof. Silvia Jurisson,** Department of Chemistry, University of Missouri-Columbia
Office: 57 Chemistry

Address: 125 Chemistry
601 S. College Avenue
University of Missouri
Columbia, MO 65211-7600
Tel: 573-882-2107
Fax:
email: **JurissonS@missouri.edu**

2) **Prof. Wynn Volkert,** Radiology Department, , University of Missouri-Columbia

Office: 330 Hadley Hall

Address: Radiopharmaceutical Sciences Institute
330 Hadley Hall
University of Missouri
Columbia, MO 65211

Phone: 573-882-2557
Fax: 573-882-6129
E-mail: **volkertw@missouri.edu**

3) **Prof. Roger Alberto,** Institute of Inorganic Chemistry, University of Zurich, Switzerland.

Office: 34-G-50

Address: Universität Zürich
Anorg.-Chem. Institut.
Winterthurerstrasse 190
CH-8057 Zurich

Phone: +41 44 63 546 31
Fax: +41 44 63 568 03

E-Mail: **ariel@aci.uzh.ch**

Rao P. Gullapalli, Ph.D., M.B.A.
Professor, Diagnostic Radiology and Nuclear Medicine
University of Maryland, Baltimore

Dr. Gullapalli worked as a Senior Clinical Scientist at Picker International (currently Philips Medical Systems) where he was responsible for developing several advanced MR imaging techniques including those related to functional imaging which eventually became main stream products. Since joining academia he has been involved in understanding longitudinal changes in structure and function following brain injury and developing image guided interventional techniques. Dr. Gullapalli heads a multidisciplinary research program centered around determining new imaging biomarkers for identifying early CNS changes following exposure to organophosphorus compounds and identifying prognostic imaging markers of traumatic brain injury on both experimental animal models and humans. He is actively involved in a multidisciplinary program to develop robot-assisted and image-guided interventions of various cancers including those of the brain and the breast. This research involves the development and application of advanced multi-parametric fMRI/MRI/MRS techniques in the diagnosis of cancer; accurate interpretation of subtle imaging changes correlated with pathology; and development of rapid real-time imaging techniques for imaging interventions. More recently he has been active in developing applications for neuro-interventions using MR guided focused ultrasound (MRgFUS). He currently directs the Core for Translational Research in Imaging @ Maryland (C-TRIM) and the Center for Metabolic Imaging and Therapeutics (CMIT) at the University of Maryland School of Medicine.

CURRICULUM VITAE

Rao P. Gullapalli, Ph.D., MBA
Professor ofDepartment of Diagnostic Radiology and Nuclear Medicine
University of Maryland School of Medicine

Date April 13, 2016

Contact Information

Business Address	Department of Diagnostic Radiology & Nuclear Medicine University of Maryland School of Medicine 22 South Greene Street Baltimore, MD 21201
Phone Number:	410-328-2099
E-mail	rgullapalli@umm.edu
Foreign Languages	Telugu, Hindi, Urdu

Education

1981 B.Tech. Chemical Engineering, Osmania University, Hyderabad, India

1982 Post-Graduate Minerals Engg Diploma, Indian Institute of Technology, Kharagpur, India

1986 M.S. Chemical Engineering, University of Arkansas, Fayetteville, AR

1991 Ph.D. Instrumental Sciences, University of Arkansas, Fayetteville, Arkansas
Thesis: Li-7 NMR of Cells and Organs in Vivo
Thesis Advisors: Dr. Richard Komoroski & Dr. Roger Hawk

2000 MBA, Case Western Reserve University, Cleveland, OH

Certifications

2002 Certified Radiology Administrator

Employment History

Academic

1983-1986	Research Assistant, Department of Chemistry & Chemical Engineering University of Arkansas, Fayetteville, AR.
1986-1991	Research Assistant, Department of Electronics & Instrumentation University of Arkansas at Little Rock, Little Rock, Arkansas.
1986-1991	Lecturer (part-time), Department of Mathematics & Statistics, UALR, University of Arkansas at Litle Rock, Little Rock, Arkansas.
1996-2004	Assistant Professor, Department of Diagnostic Radiology and Nuclear Medicine University of Maryland School of Medicine, Baltimore, MD
2004-2013	Associate Professor, Department of Diagnostic Radiology and Nuclear Medicine, University of Maryland School of Medicine, Baltimore, MD

2007-2013 Adjunct Associate Professor, Department of Bioengineering
University of Maryland College Park, College Park, MD

2013-Present Professor, Department of Diagnostic Radiology and Nuclear Medicine,
University of Maryland School of Medicine, Baltimore, MD

2013-Present Adjunct Professor, Department of Bioengineering
University of Maryland College Park, College Park, MD

Other Employment

1991-1996 Staff Scientist, Clinical Research Department, Picker International
Highland Heights, Ohio.

2007 Tenured, Associate Professor, University of Maryland School of Medicine

Professional Memberships

1989-present International Society of Magnetic Resonance in Medicine
2002-present Organization of Human Brain Mapping
2008-present National Neurotrauma Society
2015-present American College of Radiology

Honors and Awards

1982 Graduated at the top of the class for the Post-Graduate
Diploma in Minerals Engineering, Indian Institute of Technology, Kharagpur, India

1989 Full tuition scholarship to attend 'Electronics for Spectroscopists', NMR Concepts, RI.

1989 Received a student travel grant from the Society of Magnetic Resonance in Medicine to attend their eighth annual meeting in Amsterdam.

1990 Received a student grant entitled 'NMR Coils for Magnetic Resonance and Spectroscopy' Arkansas Science & Technology Authority

1990 Maurice Testerman Excellence in research award from UALR.

1995 Picker Management Award of Excellence, 1995 for contributions to the development of Echo Planar Imaging.

2007 Outstanding Invention of the Year 2007, Minimally Invasive Neurosurgical Intracranial Robot,Office of Technology Commercialization, University of Maryland College Park

Clinical Activities

Implement QA/QC procedures for diagnostic imaging

Optimize clinical imaging protocols

Train imaging technologists on the use of advanced imaging techniques

Administrative Service

Institutional Service

1998-2003 Supported Education and Training for MRI/MRSI users on
Marconi Medical Systems, GE systems, and Siemens system

1999-present Magnetic Resonance Research Committee Member

2002-present Member, Human use of Radiation Sub-committee, EHS

2002-present	Member, Radioactive Drug Research Committee, EHS
2010-2012	Member, Deans Council, University of Maryland School of Medicine
2009-present	Member, Scientific Review Committee for Patents, ORD
2007-present	Member, Research Committee, Department of Diagnostic Radiology & Nuclear Medicine, Univ of Maryland School of Medicine
2003-Present	Director, Magnetic Resonance Research, Department of Diagnostic Radiology, University of Maryland Baltimore, Baltimore, MD.
2007-Present	Director, Core for Translational Research in Imaging @ Maryland (C-TRIM) University of Maryland Baltimore, Baltimore MD
2007-2012	Co-Director, Magnetic Resonance Imaging Fellowship Program Department of Diagnostic Radiology & Nuclear Medicine
2006-Present	Section Chief, Medical Physics, Department of Diagnostic Radiology & Nuclear Medicine
2014-Present	Director, Center for Metabolic Imaging & Therapeutics (CMIT). Department of Diagnostic Radiology & Nuclear Medicine
2015-Present	Senior Editor, Journal of Medical Robotics Research.

Local and National Service

National Service

2000-present	Breast Cancer Grant Reviewer, Department of Defense
2000-present	Prostate Cancer Grant Reviewer, Department of Defense
2000-present	Ad Hoc reviewer, RSNA Research & Education Grant Reviewer
2001-present	Ad Hoc member of the Diagnostic Imaging study section and National Center for Research Resources
2010-present	Member, Special Emphasis Panel, Bioinformatics in Surgical Sciences, Biomedical Imaging and Bioengineering
2012	Ad Hoc Medical Research Council, United Kingdom
2010-Present	Ad Hoc Reviewer, American Institute of Biological Sciences
2015-Present	Senior Editor, Journal of Medical Robotics Research.
2012-Present	Organizer, CNRM Traumatic Brain Injury Symposium, Bethesda, MD
2012-Present	Organizer, Maryland Neuroimaging Retreat, Baltimore, MD

Manuscript Reviewer

1996-present	Magnetic Resonance in Medicine (1x/yr)
2014-present	Journal of Neurolgy (1x/yr)
2008-present	Journal of Digital Imaging (2x/yr)
2003-present	Journal of Magnetic Resonance Imaging (1x/yr)
2010-present	Neurotrauma (~1x/yr)
2009-present	IEEE Transactions in Biomedical Engineering (~1x/yr)
2009-present	IEEE/ASME Transactions on Mechatronics (~2/xyr)
2009-present	NMR in Biomedicine (<1x/yr)

2010	Journal of Signal Processing Systems
2008, 2011	Journal of American Statistical Association

Teaching Service

1999-Present	Radiology Physics curriculum for the residents within Department of Radiology (20- 25 residents per year)
1999-Present	Didactic lectures provided to second year radiology residents to prepare them for Radiology physics boards. (six-eight residents per year)
2007-Present	Didactic MRI Fellowship (3-5 fellows per year)
1998-Present	Responsible for Radiology Technologist training on new MRI techniques (6-8 technologists/yr)
2003-Present	(Ad Hoc) Responsible for conducting two week Summer Medical Physics camp for high-school students to make them aware of opportunities in Biomedical Imagin (12-15 students/yr)
2000-Prresent	Responsible for training and advising several graduate students in Electrical Engineering and Computer Science from the University of Maryland Baltimore County. (avg 1-2/yr)
2007-Present	GPLS 623, Molecular Toxicology (3-5 students/yr)
2008-Present	Guest Lecturer, Medical Robotics, James Clarke School of Engineering, UMCP (~20 students per class)
2007-Present	Guest Lecturer, BioE 420 Bioimaging Class, Kim School of BioEngineering, UMCP.

Students Directed

1998 Aanandhi Venkatadri, MS 1998 (Computer Science & Electrical Engineering, UMBC). Quantitative determination of cellular brain function through volumetric registration of magnetic resonance data. Role: **Thesis Advisor**.

1999 Shyamala Peri, MS 1998 (Computer Science & Electrical Engineering, UMBC). Application of novel registration algorithms in medical imaging. Independent Masters project.

2003 Rafaela Mousinho Guidi, Ph.D. 2003. (Mathematics & Statistics, UMBC) Continuum random-cluster processes simulation without critical slowing down using auxiliary variables algorithms. Role: **Thesis committee member**.

2003 Eric Moulton, Ph.D., 2003 (Neuroscience). The Cerebral Basis of Pain Intensity Encoding and its Modulation. **Thesis committee member**.

2003 Rakesh Arya, MS 2003. (Computer Science & Electrical Engineering, UMBC). Use of Independent Component Analysis to detect and eliminate physiological artifacts for improving the reliability of fMRI data. Role: **Thesis Advisor**.

2003 Sulaiman Sheriff, 2003. (Computer Science & Electrical Engineering, UMBC) Novel Initialization Method for Expectation Maximization Based Image Segmentation: Simulation and Validation. Role: **Thesis Advisor.**

2004 Novena Rangwala, MS 2004. (Computer Science & Electrical Engineering, UMBC). Quantification of Magnetic Resonance Spectroscopic Data Using Principal and Independent Component Analysis. Role: **Thesis Advisor**

2008 Bahar Zarabi, Ph.D. 2008. (Pharmaceutical Sciences) N-(2-hydroxypropyl) methacrylamide (HPMA) Copolymers for Targeted Delivery of Magnetic Resonance Contrast Agents. Role: **Thesis Committee Member**

2007 Yi Wang, MS 2007. (Computer Science & Electrical Engineering, UMBC). Kinetic Parameter Estimation Based on Independent Component Analysis of Breast Dynamic Contrast Enhanced Magnetic Resonance Imaging. Role: **Thesis Advisor**

2008 Neha Shah, MS 2008. (Computer Science & Electrical Engineering, UMBC) Functional Connectivity of the motor cortex: Test-Retest Reliability. Role: **Thesis Advisor**

2008 Bao Zhang, Ph.D. 2008. (Mechanical Engineering, UMBC) Elastic Image Registration Based on Strain Energy Minimization: Application to Prostate Magnetic Resonance Imaging. Role: **Thesis Advisor**

2009 Jiazhang Wang, MS 2009. (Computer Science & Electrical Engineering, UMBC). Evaluation Of Self-calibrated Cartesian SENSE Methods For Parallel MRI. Role: **Thesis Advisor**

2011 Tejaswini Kavallappa, MS 2011. (Computer Science & Electrical Engineering). Reliability of Structural Equation Modeling in Examining Resting State Network in Healthy Subjects. Role: **Thesis Advisor**

2011 Jiachen Zhuo, Ph.D. 2011 (Elelectrical Engineering, UMCP), Diffusion Kurtosis Magnetic Resonance Imaging and its Application to Traumatic Brain Injury. Role: **Thesis Advisor**

2012 Joshua Betz, MS 2012. Generalized Linear Models for Group Testing in Biomedical Imaging Data. Role: **Thesis Advisor**

2013 Yang Bo, Ph.D. Student (Mechanical Engineering, UMCP) Teleoperation of a MRI-Compatible Breast Biopsy Robot with Pneumatic Actuation Via Long Transmission Lines. Role: **Thesis Committee Member**

2013 Mingyen Ho, Ph.D. Student (Mechanical Engineering, UMCP) Development of a MRI-guided Intracranial Robot. Role: **Thesis Committee Member**

2013 Albert Kir, Ph.D. 2013. On Optimizing Quality and Acquisition time of SSFP-Sequence-Based Techniques for Structural and Functional MR Imaging via Extended Phase Graph. Role: **Thesis Advisor**

2014 Chandler Sours, Ph.D. 2014. Investigation of Default Mode Interference in Mild Traumatic Brain Injury. Role: **Thesis Advisor**.

2014 Elijah George, Ph.D. Evaluation of Traumatic Brain Injury Using Magnetic Resonance Spectroscopy. Role: **Thesis Advisor**

2014 Jiehua Li, Ph.D. Automatic Rodent Brain Extraction Based on a Deformable Surface Model. Role: Thesis Co-Advisor

2015 Jake Mullins, Ph.D. A Single Exposure to Chlorpyrifos during the Prepubertal Period Causes Lasting Neurological Effects: An In Vivo MR & Behavioral Study. **Thesis Advisor**.

Current Students

2011-Present Da Shi, Ph.D. Student since 2012 (Biochemsitry). Role: **Thesis Advisor**

2013-Present Shiyu Tang, Ph.D. Student in Toxicology. Functional imaging changes following exposure to pesticides **Thesis Committee Member**

2008-Present Chia Chu Chou, Ph.D. Student in Electrical Engineering. Acceleration of Electron Paramagnetic Resonance Imaging. Role: **Thesis Co-Advisor**

Grants and Contracts

Active

08/1/2010-07/31/2016
Gullapalli (PI, 10%)
Neurotoxicity of organophosphorus pesticides in developing guinea pigs
NICDHD 1RO1ES019282-01
Annual Direct Costs: $460,450
Total Direct Costs: $2,827,166

10/01/2012–09/30/2016
Gullapalli (PI 15%; PD: Desai)
MINIR-II: Minimally Invasive Neurosurgical Intracranial Robot
NIH/NIBIB 1 R01 EB015870
Annual Direct Costs: $357,588
Total Direct Costs: $1,562,717

04/01/2013-03/31/2017
Gullapalli (PI 10%; PD: Nevo)
Augmented Reality Head Mounted Display for Magnetic Resonance Imaging Guided Interventions
NIH/NCI CA168271
Annual Direct Costs: $445,741
Total Direct Costs: $1,115,278
Role: Protocol development & visualization of multiparametric images

03/27/2013-03/26/2018
Gullapalli (Co-Inv 5%l PI: Melhem/Eisenberg)
A Pivotal study to Evaluate the Effectiveness and Safety of ExAblate Transcranial MRgFUS Thalamotomy Treatment of Medication Refractory Essential Tremor Subjects.
Direct Costs: $32,000/patient
Role: assessing QA/QC and data integrity

03/27/2015-03/26/2017
Gullapalli (Co-Inv 5%; PI: Melhem/Eisenberg)
A Continued Access Study to Evaluate the Effectiveness and Safety of ExAblate Transcranial MRgFUS Thalamotomy Treatment of Medication Refractory Essential Tremor Subjects.
Direct Costs: $32,000/patient
Role: assessing QA/QC and data integrity

09/30/2013-08/31/18
Gullapalli (Co-Inv 3%; Site PI Badjatia/ PI: Manley)
NIH-NINDS 1U01NS086090-01
Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TBI)
Direct Costs: $2,113,335/y
Role: Data Integrate/QA-QC/Protocol Determination

PENDING

04/01/2013-03/31/2014
Gullapalli (PI)
Advanced Imaging Upgrade for 3.0 Tesla Scanner
NIH/ORIP 1S10OD016409-01
Annual Direct Costs: $595,350
Total Direct Costs: $595,350

04/01/2013-03/32/2016
Gullapalli (PI 10%; PD: Nevo)
MRI-guided DBS implantation system with electrophysiology monitoring
NINDS NS080447 (SBIR)
Annual Direct Costs: $262,455
Total Direct Costs: $524,911.00
Role: Interactive real-time imaging development

12/01/2015-11/30/2019
Gullapalli (MPI; Zhifeng Kuo PD)
Assessing Large-Scale Brain Network Connectivities in Traumatic Brain Injury
NIH 1R01HD086294-01
Annual Direct Costs: $250,000
Total Direct Costs: $1,000,000.00
Role: Investigate brain networks and the structural and functional connectivity among mild TBI patients.

09/01/2015-08/31/2020
Gullapalli (MPI, PI for Core; PD: Medina de Jesus)
Cortical multisensory connectivity a predictor of neurodevelopmental outcome
NIH 1P01HD085932
Annual Direct Costs: $1,000,000.00
Total Direct Costs: $7,675,000.00

COMPLETED

9/2003-3/2006
Gullapalli (Co-Inv 20.0%; PI: DiBiase)
MRSI Optimization of Prostate Brachytherapy
NCI 1R01CA092263-01A2
Annual Direct Costs:$171,052
Total Direct Costs: $347,066
Role: Provided evaluation of MR spectroscopic images

3/2004-9/2007
Gullapalli (PI: 15.0%)
Improved Sensitivity and Specificity for Prostate Cancer Detection

US Army W81XWH-04-1-0249
Annual Direct Costs: $126,540
Total Direct Costs: $253,080

4/2004-1/2008

Gullapalli (Co-Inv 10%; PI: Schweitzer)
A Compensatory Functional Neuroanatomy of ADHD
NIMH 1R01 MH066310-01A2
Annual Direct Cost:$216,719
Total Direct Cost: $902,380
Role: Analyzed functional MR images

10/01/09 – 09/30/12

Gullapalli (Co-Inv, 5%, PI: Fiskum)
The Effects of Systemic Hyperoxia and/or Hyperventilation on the Oxidative Injury and Cerebral Perfusion After TBI and Hemorrhage
US Army/Geneva Foundation W81XWH-09-2-0187
Annual Direct Costs: $227,503
Total Direct Costs: $682,509
Role: Study metabolic and structural changes following hyperoxic treatment.

7/2004-7/2006

Gullapalli (Co-Inv 2.5%; PI: Regenold)
Mood Disorders and Diabetes: Common Disease Mechanisms
NIMH R21-MH006028
Annual Direct Costs: $150,000
Total Direct Costs: $275,000
Role: Analyzed diffusion tensor images

5/2005-4/2007

Gullapalli (PI 5.0%)
High field animal magnetic resonance imaging system
NCRR/NIH 1S10RR019935-01
Annual Direct Costs: $1,978,000
Total Direct Costs: $1,978,000

5/2005-4/2008

Gullapalli (Co-Inv 10.0%; PI: Mezrich)
Siemens MR Research Collaboration
Siemens Medical Systems
Annual Direct Costs: $140,000
Total Direct Costs: $539,000
Role: Developed novel pulse sequences

8/2006-7/2007

Gullapalli (PI: 10.0%)
Advanced Functional MRI Equipment for 3 Tesla System
NCRR/NIH: 1S10RR019214
Annual Direct Costs: $362,195
Total Direct Costs: $362,195

9/2006-8/2007

Gullapalli (PI: 10.0%)
Etiology of Spinal Cord Injury Assessed by Advanced MR Techniques& Longitudinal Evaluation of Glibenclamide Treatment
Grant Number: School of Medicine Intramural Grant
Annual Direct Costs: $63,750
Total Direct Costs: $63,750

1/2007-05/2012

Gullapalli (Co-PI 10.0%; PI: Albuquerque)
Age and sex effects on nerve agent damage to the brain and antidotal therapies
NIH/NINDS 1U01NS059344-01
Annual Direct Costs: $473,808
Total Direct Costs: $2,475,456
Role: Structural and metabolic evaluation of nerve agent induced damage to

determine sensitive marker

09/2007-09/2008

Gullapalli (PI: 5.0%)
Small Animal Positron Emission Tomography for Translational Research
NCRR/NIH: 1S10RR023583-01A1
Annual Direct Costs: $500,000
Total Direct Costs: $500,000

09/2007-09/2008

Gullapalli (PI: 5.0%)
Small Animal Micro CT System for Translational Research
Siemens Molecular Imaging, Siemens Medical Solutions
Annual Direct Costs: $400,000
Total Direct Costs: $400,000

09/01/2011-08/31/2013

Gullapalli (Co-Inv 5%; PI:Albuquerque)
Developmental Neurotoxicity of Sarin and Soman in Guinea Pigs
NIH/NINDS 5R21NS076429
Annual Direct Costs: $250,000
Total Direct Costs: $500,000
Role: Investigate time course of biophysical and biochemical changes

11/2007-10/2009

Gullapalli (Co-Inv 10.0%; PI: Wittenberg)
Biological prediction & correlation of response to robotic arm therapy
Grant Number: 4946 Veterans Administration Rehabilitation & Development Merit Review Award
Annual Direct Costs: $250,000
Total Direct Costs: $500,000
Role: Provided functional MRI data analysis support

8/2008-7/2010

Gullapalli (Site PI: 5.0%; PI: Desai)
MINIR-Minimally Invasive Neurosurgical Intracranial Robot
NIBIB/NIH 1R21EB008796
Total Annual Costs: $150,000
Total Direct Costs: $275,000
Roe: Site PI and developed real-time image tracking methods

7/2009-7/2010

Gullapalli (PI 5.0%)
Weinberg Medical Physics Project
Grant Number: 00004396, Weinberg Medical Physics LLC
Annual Direct Costs: $50,000
Total Direct Costs: $50,000

1/1998-12/2000

Gullapalli (Co-Inv 5.0%l PI: NessAiver)
Application of Opto-Electronic Implementation of the 2D Discrete Fourier Transform to Real Time Construction of Non-Rectilinear MRI Data Sets
Whitaker Foundation
Total Annual Costs: $134,000
Total Direct Costs: $168,000
Role: Provided image reconstruction support

7/1999-6/2000

Gullapalli (PI: 10.0%)
Non-Invasive Monitoring of Citrate Levels in Prostate Using Magnetic Resonance Spectroscopic Imaging (MRSI)
University of Maryland School of Medicine Intramural Grant

5/1999-4/2000

Gullapalli (PI: 15.0%)
Regional Cerebral Blood Flow at Rest and Task Dependent Activation in the Supplementary Motor Cortex: Correlating Baseline Perfusion with Functioinal MRI

Radiology Society of North America
Total Annual Costs: $25,000
Total Direct Costs: $25,000

6/2000-6/2001

Gullapalli (PI: 10.0%)
Advanced Hardware and Software for Magnetic Resonance Research
Marconi Medical Systems
Total Annual Costs: $385,000
Total Direct Costs: $385,000

4/2001-3/2004

Gullapalli (Co-Inv 10.0%; PI: Burton)
The Neural Basis of Normal and Impaired Phonology
NIDCD R01-DC04201
Total Annual Costs: $291,666
Total Direct Costs: $875,000
Role: provided fMRI acquisition and data analysis support

6/2003-5/2004

Gullapalli (PI: 20.0%)
Effect of Age on Cortical Responses to Nociception
NIH/NIA RO3 AG022223-01
Total Annual Costs: $50,000
Total Direct Costs: $50,000

02/2000 - 01/2004

Gullapalli (Co-Inv 20%; PI: Greenspan)
Cerebral Processing and Human Somesthetic Perception
NIH/NINDS R01 NS-39339
Annual Direct Costs: 173,649
Total Direct Costs: $694,599
Roe: Provided fMRI data acquisition and analysis support

09/15/2008-09/14/2014

Gullapalli (PI, 10%)
Investigation of Prognostic Ability of Novel Imaging Markers for Traumatic Brain Injury (TBI)
DOD W81XWH-08-1-0725
Annual Direct Costs: $222,169
Total Direct Cost: $673,957

07/01/2008-06/30/2014

Gullapalli (Co-Inv, 10%; PI: Desai)
Robotic Haptic Feedback System for Bx/RFA of Breast Tumor under Continuous MRI
NIBIB/NCI RO1 EB008713-01
Annual Direct Costs: $202,309
Total Direct Costs: $839,504
Role: Develop suitable real-time imaging & thermometry methods

05/01/2011-08/13/2015

Gullapalli (Co-Inv 5%; PI:Pereira)
Nerve Agent Countermeasure for Sub-Lethal Exposures
Countervail Corporation through BARDA HHS01 002011 00030C
Annual Direct Costs (for this year): $290,256
Total Direct Costs(for this year): $290,256
Role: Study imaging changes following injury and provide in vivo assessment of the effectiveness of galantamine

04/02/2012-10/01/2014

Gullapalli (PI, 10%)
Evaluation of Diffusion Kurtosis Imaging in Traumatic Brain Imaging
US Army W81XWH-12-1-0098
Annual Direct Costs: $198,083
Total Direct Costs: $198,083

7/2002-12/2014	Gullapalli (Co-Inv 5.0%; PI: Hochberg) Clinical Centers for the Osteoarthritis Initiative NIH-NIAMS N01AR22259-13-0-1 Annual Direct Costs: $953,096 Total Direct Costs: unknown Role: Manage the complete MR imaging operations for the study
5/2009-4/2015	Gullapalli (Co-Inv 5.0%; PI: Stone) Predictors of Speech Quality after Tongue Cancer Surgery NIH/NCI 5R01CA133015 Annual Direct Costs: $ 322,812 Total Direct Costs: $1,333,974 Role: Development of tagging pulse sequences & data analysis
05/01/2011-11/30/2012	Gullapalli (UMB PI) Influence of High Strain Induced Intercellular Moisture Flow on Brain Tissue Material Properties UMCP-UMB Seed Program Annual Direct Costs: $75,000 Total Direct Costs: $75,000
07/01/2012-06/30/2013	Gullapalli (Co-Inv, PI: Mistry; Varshney) Improving Cancer Foci Detection in Prostate Cancer Using Multiparametric MRI/MRS and Machine Learning to better manage the disease. UMB-UMCP Seed Program Annual Direct Costs:$75,000 Total Direct Costs: $75,000 Role: Protocol development and interpretation of spectroscopic data
02/01/2011-01/31/2016	Gullapalli (Co-Inv, 10%, PI: McKenna) Metabolic & Development Aspects of Mental Retardation NICHD/NIH PO1 HD016596-25 Current Year Direct Costs: $626,229 Total Direct Costs to date: $1,245,431 Role: Study the time course of imaging changes (MR and PET) to study development following Hypoxic-ischemic injury
9/2009-8/2015	Gullapalli (Co-Inv 5.0%; PI: Waldstein) HANDLS Scan Substudy: Race, Socioeconomic Status, and the Brain NIH/NIA 5R01AG034161-04 Annual Direct Costs: $373,961 Total Direct Costs: $1,644,406 Role: Protocol development and resting state data analysis
04.01.2014-03/31/2016	Gullapalli (Pi 10%) Traumatic Brain Injury Data for FITBIR Informatics System NINDS R03NS088014 Annual Direct Costs: $100,000 Total Direct Costs: $100,000 Role: Fortify the FITBIR data base with traumatic brain injury data
10/01/2012-9/30/2015	Gullapalli (Co-Inv 10%; PI: Shanmuganathan) Do Admission DTI Parameters Predict Outcome in Traumatic Cervical SCI NINDS/NIBIB 1 R01 NS080865 Annual Direct Costs: $250,000 Total Direct Costs: $750,000 Role: pulse sequence development & evaluation of data

Patents, Inventions and Copyrights

1. H. Liu, **R.P. Gullapalli**, M. Loncar, and G. DeMeester; *Magnetic Resonance Scan Calibration Method for Ultra-Fast Image Acquisition*, U.S. Patent No. 5,621,321, **Eur Patent No. 96307627.8-1234**.
2. H.Liu, **R.P. Gullapalli**, and M. Loncar; *An Ultra-Fast MR Imaging Data Acquisition Scheme using Mixed Bandwidth Data*, **U.S. Patent No. 5,602,476; European Patent No. 96305556.1-1234**.
3. **R.P. Gullapalli**, H. Liu, and M. Loncar; *Three Point Method for Producing Water/Fat Images Derived from FSE/GRASE Sequences*, **U.S. Patent No. 5,594,336; European Patent No. 96303300.6-1234.**
4. M. Loncar, J.B. Murdoch, and **R.P. Gullapalli**; *An Efficient Method of Spoiling Transverse Magnetization for both Spectral and Spatial Saturation Techniques*, **U.S. Patent No. 5,500,593**, **European Patent No. 95307686.6-2204**.
5. **R.P. Gullapalli**, J.V. Hajnal, H. Liu, and L. Kasuboski; *Interleaved Slab Inversion for Enhanced Throughput of the FLAIR Technique*, **U.S. Patent No. 5,528,144**.
6. L. Kasuboski, and **R.P. Gullapalli**; *Dipolar Weighted MR Imaging In-Vivo*, **U.S. Patent No. 5,345,175**.
7. J. Hallamek, M. Loncar, & **R.P. Gullapalli**; *Respiratory Motion Compensation using Segmented k-space Magnetic Resonance Imaging*, **U.S. Patent No. 5,766,128.**
8. **R.P. Gullapalli**, & M. Loncar; *An Ultra-Fast Imaging Technique using k-Space Segmentation with Minimum Phase and Amplitude Errors*, **U.S. Patent No. 5,825,184.**
9. **R.P. Gullapalli**, M. Loncar, & P.M. Margosian; *BATch Multi-volume ANgiography (BatMAn) using Magnetic Resonance Imaging*, **U.S. Patent No. 5,786,693**. **Eur Patent No. 97301433.5-1270**.
10. **R.P. Gullapalli**, & M. Loncar; *Dual Contrast Fast Spin Echo with Alternating Phase Encode Map***, US Patent No. 6,075,362**
11. A.B. McMillan, **R.P.Gullapalli**, H. Richard, S. Roys. J.P.Desai. *Real Time Tracking and Navigation System for Minimally Invasive Surgery*. UMB Docket No.AM-2011-082, Provisional patent filed on 4-26-2012; Application No. 61638769
12. J.P. Desai, J.M. Simard, **R.P. Gullapalli**, M. Ho. *MINIR: Minimally Invasive Intracranial Interventional Robot.* Docket No. RG-2012-008; filed 7-27-2011.

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Journal Articles (Peer Reviewed)

1. **Gullapalli RP**, Hawk RM, Komoroski RA; *A ^{7}Li NMR Study of Visibility, Spin Relaxation, and Transport in Normal Human Erythrocytes*, Magn Reson Med 1991;20:240-252. PMID:1775050.
2. **Gullapalli RP**, Hawk RM, Komoroski RA; *Effect of Lithium on the Double-Quantum Behavior of ^{23}Na in Normal Human Erythrocytes,* Magn Reson Med 1992;27:1-12. PMID:1435196.
3. Finelli DA, Hurst GC, **Gullapalli RP**, Bellon EM; *Improved Contrast of Enhancing Brain Lesions on Post-Gadolinium, T1-weighted Spin Echo Images with use of Magnetization Transfer*. Radiology 1994;190(2):553-559.
4. Finelli DA, Hurst GC, **Gullapalli RP**; *Magnetization Transfer Doubles the Contrast-to-Noise Ratio of Enhancing Lesions on 3D RF-Spoiled GRE Images of the Brain*. Radiology 1995;v197(P): 409.
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10. Hlustik P, Solodkin A, **Gullapalli RP**, Noll DC, Small SL*, Somatotopy in Human Primary Motor and Somatosensory Hand Representations Revisited*, Cerebral Cortex, 11:312-321, Apr 2001.
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5 Diffusion Kurtosis in the Evaluation of Traumatic Brain Injury National Capital Region TBI Research Symposium, Washington DC, April 5, 2011
6 Diffusion Kurtosis as a Novel Imaging Marker for Traumatic Brain Injury - Correlation with Histology Federal Interagency Conference on Traumatic Brain Injury, Washington DC, June 14, 2011.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	WAYNE R. ROBERTS, CHIEF EXECUTIVE OFFICER
SUBJECT:	SECTION 102.1062 WAIVER – DR. BECKY GARCIA
DATE:	MAY 11, 2016

Waiver Request and Recommendation

I request that the Oversight Committee approve a conflict of interest waiver for FY 2016 for Program Integration Committee ("PIC") member Dr. Becky Garcia, pursuant to Health & Safety Code Section 102.1062 "Exceptional Circumstances Requiring Participation." Dr. Garcia recently accepted an appointment to the advisory committee serving the Texas Health Improvement Network, a statutorily-created program that is administratively attached to The University of Texas System. The waiver is necessary for Dr. Garcia to participate in CPRIT's review process as a PIC member. Together with the waiver's proposed limitations, adequate protections are in place to mitigate the opportunity for the award of grant funds to be driven by anything other than merit and established criteria.

Background

In 2015, the Legislature created the Texas Health Improvement Network ("THIN") with the purpose to "address urgent health care challenges and improve the health care system in this state and the nation and to develop, based on population health research, health care initiatives, policies, and best practices." Texas Health and Safety Code § 118.051(a). By statute, THIN is administratively attached to the University of Texas System, which coordinates the program and provides administrative support. Texas Health and Safety Code § 118.054. Dr. Garcia, CPRIT Chief Prevention Officer, was appointed to serve on the advisory council that advises THIN on health care needs of Texas.

Texas Health & Safety Code § 102.106(c)(1) holds that a professional conflict of interest exists if a PIC member is a member of any committee affiliated with an entity receiving or applying to receive money from CPRIT during the same grant cycle. The University of Texas System is composed of several institutions, many of which are current CPRIT grantees, including, but not limited to, UT Southwestern Medical Center, M.D. Anderson Cancer Center, and UT Health Science Center at San Antonio. Since Dr. Garcia serves on a committee administered by a university system that includes CPRIT grantees, a professional conflict of interest arises.

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CPRIT's administrative rule § 702.17(3) authorizes the Oversight Committee to approve a waiver that applies for all activities affected by the conflict during the fiscal year.

Exceptional Circumstances Requiring Dr. Garcia's Participation

In order to approve a conflict of interest waiver, the Oversight Committee must find that there are exceptional circumstances justifying the conflicted individual's participation in the review process. The statute compels the Chief Prevention Officer's participation in the review process as a PIC member. In order to fulfill legislative intent that the Chief Prevention Officer serve as a PIC member, the proposed waiver should be granted. The proposed limitations will substantially mitigate any potential for bias.

Proposed Waiver and Limitations

In granting the waiver of the conflict of interest set forth in Section 102.106(c)(1), I recommend that Dr. Garcia be permitted to continue to perform the following activities and duties associated with CPRIT's review process subject to the stated limitations:

1. If THIN submits an application for a CPRIT grant award, Dr. Garcia must recuse herself from any discussion, review and vote related to the application.
2. If a principal investigator applying for CPRIT funds has also received funds from THIN for the same project, Dr. Garcia must recuse herself from any discussion, review and vote related to the application.

CPRIT's Chief Compliance Officer is statutorily required to attend PIC meetings to document compliance with CPRIT's rules and processes, including adherence to this limitation. The Compliance Officer shall report to the Oversight Committee any violation of this waiver prior to the Oversight Committee's action on the PIC recommendations.

Important Information Regarding this Waiver and the Waiver Process

- The Oversight Committee may amend, revoke, or revise this waiver, including but not limited to the list of approved activities and duties and the limitations on duties and activities. Approval for any change to the waiver granted shall be by a vote of the Oversight Committee in an open meeting.
- This waiver is limited to the conflict of interest specified in this request. To the extent that Dr. Garcia has a conflict of interest with an application that is not the conflict identified in Section 102.106(c)(1), then Dr. Garcia will follow the required notification and recusal process.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	CHIEF OPERATING OFFICER REPORT
DATE:	MAY 9, 2016

CPRIT Financial Overview for FY 2016, Quarter 2

FY 2016, Quarter 2 Operating Budget

For the second quarter of FY 2016, CPRIT has expended or encumbered approximately $13.1 million, or 78%, of the agency's $16.7 million administrative budget between the Indirect Administration and Grant Review and Award Operations strategies. This administrative budget includes approximately $208,000 in expenses for the 2015 conference. Otherwise, the primary items of expenditure remain staff salaries and service contracts, particularly the contract with SRA International for pre- and post-award grant management support services.

During this quarter, CPRIT received $21,122 in revenue sharing payments which was deposited into the General Revenue Fund (0001). Total revenue sharing payments received since CPRIT's inception are approaching $2.3 million. CPRIT collected more than $223,000 in conference registration fees. The difference of $15,000 between the amount collected in registration fees and the conference expenses can be used by CPRIT toward the conference planned for 2017.

FY 2016, Quarter 2 Performance Measures

In March 2016, CPRIT reported second quarter performance to the LBB on the two output measures that have quarterly reporting requirements:

1) Number of People Served by Institute Funded Prevention and Control Activities and
2) Number of Entities Relocating to Texas for Cancer Research Related Projects.

Debt Issuance History

The Texas Public Finance Authority (TPFA) issued $125.2 million in commercial paper notes on CPRIT's behalf since the beginning of fiscal year 2016.

State Strategic Planning for the 2018-19 Biennium

On April 6, 2016, the Governor's Office and Legislative Budget Board (LBB) jointly issued instructions about preparing and submitted agency strategic plans covering fiscal years 2017 through 2021. The required elements in the agency strategic plan have been greatly reduced from prior years which will streamline the plan to be submitted. CPRIT's strategic plan is due by June 24, 2016, to the Governor's Office, LBB and other legislative oversight offices. The agency strategic plan does not require action by the Oversight Committee but will require the Oversight Committee Presiding Officer's signature. We will forward the CPRIT Strategic Plan for 2017 to 2021 to the Oversight Committee when complete.

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Each agency strategic plan must include the agency mission and the agency goals and action plan. Agencies may also include redundancies and impediments related to services, state statutes, and state rules and regulations as applicable. The other elements that will be included in CPRIT's strategic plan are the:

1) Budget structure,
2) List of measure definitions,
3) Historically Underutilized Business Plan,
4) Agency workforce plan, report on customer service, and
5) Assessment of advisory committees.

As part of strategic planning, agencies have the opportunity to address issues with their budget structures and performance measures. CPRIT submitted a request to the LBB and Governor's Office to amend the name and measure definition of one of the prevention program performance measures to count services provided rather than people served which can produce duplicate numbers, remove a compliance measure related to grantee reporting delinquencies, and add a new compliance measure about grantees receiving required training. No changes to the budget structure were requested, so the structure should remain four strategies:

1) Award Cancer Research Grants (include academic and product development research)
2) Award Cancer Prevention Grants
3) Grant Review and Award Operations
4) Indirect Administration

This structure will be used in the preparation of the agency's Legislative Appropriations Request (LAR) which is the next step in preparing the state budget for the 2018-19 biennium.

Cancer Prevention and Research Institute of Texas
LBB Quarterly Financial Report
As of February 29, 2016

Indirect Administration (B.1.1.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 1,413,921	$ 1,064,491		$ 614,235	450,256	58%	$ 614,235	$ 450,256
1002	Other Personnel Costs	51,000	51,000		8,109	42,891	16%	8,109	42,891
2001	Professional Fees and Services	1,015,500	947,015		762,328	184,687	80%	762,328	184,687
2003	Consumable Supplies	26,651	26,651		9,270	17,381	35%	9,270	17,381
2004	Utilities	64,921	64,921		9,485	55,436	15%	9,485	55,436
2005	Travel	36,095	36,095		24,187	11,908	67%	24,187	11,908
2006	Rent-Building	-	18,485		18,486	(0)	0%	18,486	(0)
2007	Rent-Machine and Other	24,995	24,995		11,319	13,676	45%	11,319	13,676
2009	Other Operating Expenses	349,402	819,480		146,914	672,566	18%	146,914	672,566
	Subtotal - Indirect Administration (B.1.1.)	**$ 2,982,485**	**$ 3,053,133**	**1.03%**	**$ 1,604,333**	**$ 1,448,801**	**53%**	**$ 1,604,333**	**$ 1,448,801**

Grant Review and Award Operations (A.1.3.)

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
1001	Salaries and Wages	$ 2,679,624	2,686,966		$ 1,364,075	$ 1,322,891	51%	$ 1,364,075	$ 1,322,891
1002	Other Personnel Costs	3,726	3,726		22,747	(19,021)	0%	22,747	(19,021)
2001	Professional Fees and Services	11,040,000	11,646,352		9,839,707	1,806,645	84%	9,839,707	1,806,645
2003	Consumable Supplies	-	-		-	-	0%	-	-
2005	Travel	42,516	42,516		26,983	15,533	63%	26,983	15,533
2006	Rent - Building	33,534	33,534		16,410	17,124	49%	16,410	17,124
2007	Rent-Machine and Other	7,763	7,763		1,662	6,101	21%	1,662	6,101
2009	Other Operating Expenses	-	82,300		1,750	80,550	2%	1,750	80,550
	Conference		244,532		212,162	32,370	87%	212,162	32,370
	Subtotal - Grant Operations (A.1.3.)	**$ 13,807,163**	**$ 14,747,689**	**4.96%**	**$ 11,485,497**	**$ 3,262,192**	**78%**	**$ 11,485,497**	**$ 3,262,192**

Grants

		2016 Appropriated	2016 Budgeted	% of Total Budget	Actual Expenditures & Grant Encumbrances (FYTD)	Remaining Budget	Percent Expended	Estimated Expenditures (YTD)	Lapse/Overspent
4000	Grants - Prevention (A.1.2)	$ 28,340,035	$ 27,980,885		$ 13,247,742	$ 14,733,143	47%	$ 13,247,742	$ 14,733,143
4000	Grants - Research (A.1.1.)	251,955,763	$ 251,692,961		98,761,270	$ 152,931,691	39%	98,761,270	152,931,691
	Subtotal - Grants	**$ 280,295,798**	**$ 279,673,846**	**94.02%**	**$ 112,009,012**	**$ 167,664,834**	**40%**	**$ 112,009,012**	**$ 167,664,834**
	Grand Totals	**$ 297,085,446**	**$ 297,474,668**	**100.00%**	**$ 125,098,842**	**$ 172,375,827**	**42%**	**$ 125,098,842**	**$ 172,375,827**

Cancer Prevention and Research Institute of Texas

Cancer Prevention and Research Institute Fund Account - 5136

As of February 29, 2016

	02/01/2016 thru 02/29/2016	AY 16 Year to Date as of 02/29/2016
Beginning Balance : 02/01/2016		**$ 600,506**
Increases:		
(1)	$ -	$ -
(2)	-	
Total Increases	**$ -**	**$ 600,506.00**
Reductions:		
Expenditures - Appropriated	$ -	$ -
	$ -	$ -
	$ -	$ -
Total Reductions	**$ -**	**$ -**
Ending Balance, 02/29/2016		**$ 600,506.00**

Note: (1) The Institute received a settlement from the Texas Cancer Coalition (TCC). This amount represents the final distribution and transfer of all funds ($303,877) from the TCC which ceased operations in May 2013. These funds are in the State Treasury but are not appropriated to CPRIT. The beginning balance reflects the transfer of all TCC funds.

Cancer Prevention and Research Institute of Texas

License Plate Trust Fund Account - 0802

As of February 29, 2016

	02/01/2016 thru 02/29/2016	AY 16 Year to Date as of 02/29/2016
Beginning Balance : 02/01/2016		**$ -**
Increases:		
(1) License Plate Revenue Received	$ 1,173.41	$ 6,898.89
Total Increases	**$ 1,173.41**	**$ 6,898.89**
Reductions:		
Expenditures - Appropriated	$ 0.00	$ 0.00
	-	-
	-	-
Total Reductions	**$ 0.00**	**$ 0.00**
Ending Balance, 02/29/2016		**$ 6,898.89**

Note:

Cancer Prevention and Research Institute of Texas

Appropriated Receipts - 666

As of February 29, 2016

		02/01/2016 thru 02/29/2016	AY 16 Year to Date as of 02/29/2016
Beginning Balance : 02/01/2016			**$ 62,102.00**
Increases:			
(1)	Product Development Application Fees Received	$ 16,000.00	$ 41,000.00
(2)	Appropriated Receipts applied to payments	$ -	$ -
(3)	Conference Registration Fees	$ 6,290.00	$ 182,430.00
(4)	Conference Registration Fees-Credit Card	$ 10.71	$ 4,133.61
Total Increases		**$ 22,300.71**	**$ 227,563.61**
Reductions:			
	Conference Expenditures - Appropriated	$ (2,919.61)	$ (208,028.59)
	Credit Card Fees Expended	$ (20.59)	$ (4,133.61)
		$ -	$ -
Total Reductions		**$ (2,940.20)**	**$ (212,162.20)**
Ending Balance, 02/29/2016			**$ 77,503.41**

Cancer Prevention and Research Institute of Texas

General Revenue Fund Account - 0001

As of February 29, 2016

		02/01/2016 thru 02/29/2016	AY 16 Year to Date as of 02/29/2016
Beginning Balance : 02/01/2016			**$ -**
Increases:			
(1)	Revenue Sharing / Royalties	$ -	$ 36,198.28
Total Increases		**$ -**	**$ 36,198.28**
Reductions:			
	Expenditures - Appropriated	$ -	$ -
	Sweep Account	$ -	$ (36,198.28)
		$ -	$ -
Total Reductions		**$ -**	**$ (36,198.28)**
Ending Balance, 02/29/2016			**$ -**

Note:

Cancer Prevention and Research Institute of Texas
FY 2016, Quarter 2 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	114,072	125,498			239,570	29.95%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00	0.00			0.00	0.00%
Percentage of Texas Regions with Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A		0.00%
Annual Age-adjusted Cancer Mortality Rate	155.3	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter. CPRIT does not anticipate meeting the targeted number, which was doubled from the prior year, as the funded grant activities have not changed significantly from year to year.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

Cancer Prevention and Research Institute of Texas
FY 2016, Quarter 1 Performance Measure Report

Measure	Targeted Performance	QTR 1	QTR 2	QTR 3	QTR 4	Sum of QTRs	% of Mandate Attained
Number of People Served by Institute Funded Prevention and Control Activities	800,000	114,072				114,072	14.26%
Number of Entities Relocating to TX for Cancer Research Related Projects	2.00	0.00				0.00	0.00%
Percentage of Texas Regions with Cancer Prevention Services and Activities Initiated	100%	N/A	N/A	N/A	N/A		0.00%
Annual Age-adjusted Cancer Mortality Rate	155.3	N/A	N/A	N/A	N/A		0.00%
Number of Published Articles on CPRIT-Funded Research Projects	450	N/A	N/A	N/A	N/A		0.00%
Number of New Jobs Created and Maintained	315	N/A	N/A	N/A	N/A		0.00%

Variance Explanations

Number of People Served by Institute Funded Prevention and Control Activities
CPRIT grantees deliver these education and clinical services throughout the year, so the reported number of people served is not allocated evenly for each fiscal quarter.
Number of Entities Relocating to TX for Cancer Research Related Projects
This output is dependent on the number of companies applying for CPRIT Company Relocation Awards that can successfully advance through CPRIT's rigorous review and evaluation process, receive an award and actually relocate operations to Texas.

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2010	$ 225,000,000	September 9, 2009	$ 9,100,000		Commercial Paper Notes	Series A, Taxable		
2010		September 9, 2009	$ 3,600,000		Commercial Paper Notes	Series B, Tax-Exempt	Defeased with cash July 2011	
2010		March 12, 2010	$ 63,800,000		Commercial Paper Notes	Series A, Taxable		
2010		August 26, 2010	$ 148,500,000		Commercial Paper Notes	Series A, Taxable		
				$ 225,000,000				
2011	$ 225,000,000	September 7, 2010	$ 11,800,000		Commercial Paper Notes	Series A, Taxable		
2011		August 10, 2011	$ 50,775,000		G.O. Bonds	Taxable Series 2011	Par amount of new money	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
2011		August 10, 2011	$ 232,045,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2011	Par amount of refunding; Refunded $233.2M of GOCP CPRIT Series A (9/9/09, 3/12/09, 8/26/09, 9/7/10)	Fixed Rate Bonds All-In-True Interest Cost 4.0144%
				$ 62,575,000				
2012	$ 300,000,000	September 7, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		December 8, 2011	$ 3,200,000		Commercial Paper Notes	Series A, Taxable		
2012		March 2, 2012	$ 12,300,000		Commercial Paper Notes	Series A, Taxable		
2012		June 21, 2012	$ 15,000,000		Commercial Paper Notes	Series A, Taxable		
2012		August 16, 2012	$ 42,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 75,700,000				
2013	$ 300,000,000	September 6, 2012	$ 9,600,000		Commercial Paper Notes	Series A, Taxable		
2013		May 16,2013	$ 13,400,000		Commercial Paper Notes	Series A, Taxable		
				$ 23,000,000				
2014	$ 300,000,000	November 25, 2013	$ 55,200,000		Commercial Paper Notes	Series A, Taxable		
2014		March 13, 2014	$ 47,000,000		Commercial Paper Notes	Series A, Taxable		
2014		June 17, 2014	$ 60,300,000		Commercial Paper Notes	Series A, Taxable		
2014		July 8, 2014	$ 233,280,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2014	Par amount of refunding; Refunded $237.88M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.327184%
				$ 162,500,000				
2015	$ 300,000,000	November 5, 2014	$ 57,600,000		Commercial Paper Notes	Series A, Taxable		
2015		April 29, 2014	$ 112,000,000		Commercial Paper Notes	Series A, Taxable		
2015		June 26, 2015	$ 75,000,000		Commercial Paper Notes	Series A, Taxable		
				$ 244,600,000				

CPRIT Commercial Paper and G.O. Bond Issuance

Fiscal Year	Amount Appropriated	Dated Issued	Amount Issued	Amount Issued for Fiscal Year	Commercial Paper or GO Bond Issuance	Series	Comments	Interest Rate
2016	$ 300,000,000	September 22, 2015	$ 55,400,000		Commercial Paper Notes	Series A, Taxable		
2016		October 29, 2015	$ 300,000,000		G.O. Bonds (Refunding Bonds)	Taxable Series 2015C	Par amount of refunding; Refunded $300M of GOCP CPRIT Series A	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
2016		October 29, 2015	$ 69,800,000		G.O. Bonds	Taxable Series 2015C	Disbursed to CPRIT January 2016	Fixed Rate Bonds All-In-True Interest Cost 3.299867%
				$ 125,200,000				
TOTAL ISSUED TO DATE				**$ 918,575,000**				

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

To:	**OVERSIGHT COMMITTEE MEMBERS**
From:	**HEIDI MCCONNELL, CHIEF OPERATING OFFICER**
Subject:	**PROVISIONAL APPROVAL OF THE LEGISLATIVE APPROPRIATIONS REQUEST ITEMS FOR 2018-19 BUDGET**
Date:	**MAY 1, 2016**

Recommendation
CPRIT staff recommends that the Oversight Committee provisionally approve the items to be requested (attachment) in the agency's Legislative Appropriations Request (LAR) for the 2018-19 biennium at the May 18th Oversight Committee meeting. The LAR will not be in a final form for approval at the Oversight Committee meeting because state agencies have just begun the strategic planning process which must be completed before work on the LAR can begin. Based on the LAR submission schedule in previous years, staff believes that CPRIT's LAR will be due to the Governor's Office and Legislative Budget Board (LBB) in early August prior to the Oversight Committee meeting scheduled that month.

As part of this provisional approval, CPRIT staff must present the drafted LAR to the Audit Subcommittee at a to-be-scheduled mid-summer meeting. The Audit Subcommittee will review the LAR to confirm that the content is consistent with the list of LAR request items provisionally approved by the Oversight Committee in May. After the Audit Subcommittee affirms that the content is consistent with items approved by the Oversight Committee, staff would send the LAR to the presiding officer for his signature and then submit the LAR to the Governor's Office, LBB, and other required legislative oversight offices.

Note that if the Audit Subcommittee determines that the LAR is inconsistent with the list of LAR request items provisionally approved by the Oversight Committee, CPRIT will convene a special meeting of the Oversight Committee to approve the LAR before the submission deadline.

Background
On April 6, the Governor's Office and LBB jointly issued instructions to state agencies for preparing and submitting their strategic plans for fiscal years 2017 through 2021. The submission of the agency's strategic plan is the first step in developing the state budget for the 2018-19 biennium which will be considered by the Texas Legislature when they convene for the 85th Regular Session in January 2017. CPRIT's strategic plan is due by June 24, 2016.

LAR instructions for state agencies have not yet been issued by the Governor's Office and LBB. An agency's LAR is based on the approved budget structure which is part of the strategic plan. The budget structure must be approved by both offices. Therefore, CPRIT cannot begin preparing the LAR in the required format until this approval is secured.

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Possible Requests Included in the Legislative Appropriations Request to the 85th Texas Legislature

REQUEST	EXPLANATION
Request FTE increase	Three (3) additional FTEs would provide additional support in compliance and grant accounting. The agency currently has a cap of 32 FTEs.
Add new rider to appropriate any bond premiums earned above the bond proceed amounts to pay issuance costs of the bonds.	The rider would maximizes the amount of funds available for cancer projects by clarifying that bond premiums earned above the bond proceed amounts can pay the costs of issuing bonds. Currently bond issuance costs are paid from bond proceeds which reduces funds for awards. *Requested in prior sessions.*
Modify Rider 4, Transfer Authority, to allow CEO to report transfers within the limitations of Art. IX, Sec. 14.01 Appropriations Transfers allowed other state agencies	Allowing CEO notification to the LBB and Governor about agency transfers within the 20% transfer limit from one budget line item to another, excluding indirect administration, would provide CPRIT the same authority as other agencies and maximize operational efficiency. The current rider requires CPRIT to receive approval from those two offices before budget transfers between line items can occur. *Requested in 2015.*
Strike Rider 5, Transfer to DSHS for Cancer Registry	The transfer reduces CPRIT's available grant funds by $6 million over the biennium to fund the Texas Cancer Registry, an activity not managed by CPRIT. Furthermore, bond proceeds in addition to the required transfer amount for Cancer Registry operations are being drawn down by ERS to fund insurance contributions for retired Cancer Registry employees pursuant to GAA. Art IX, Sec. 6.08, Benefits Paid Proportional by Fund.
Strike Rider 7, Limitation on Expenditure for Contracts	The current rider requires LBB approval of all contracts in excess of $250,000. LBB approval of contracts is generally not required of other agencies and is redundant to the Oversight Committee's approval of all major contracts of $100,000 or more. Waiting for LBB approval can delay critical agency operations. *Requested in 2015.*
Request an increase in the CEO Exempt Salary amount in the Administrator's Statement	The CEO salary cap should be increased to have a recruitment incentive in the event the agency has to hire a new CEO and provides room for merit incentives to CEO.
Request Interest & Sinking Fund exemption from funds consolidation in the Administrator's Statement	Health and Safety Code, Sec. 102.270 allows the creation of the Interest & Sinking Fund, a GR-Dedicated account, to receive revenue sharing payments from patent, royalty, and license agreements. Funds from this account could be used to pay off debt service on CPRIT GO bond issuance or fund new awards. The Fund needs to be exempted in the funds consolidation bill so it can be created in the Treasury and receive deposits of revenue sharing payments. *Requested in 2015.*

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO	OVERSIGHT COMMITTEE MEMBERS
FROM	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT	PROVISIONAL APPROVAL OF THE GRANT MANAGEMENT SUPPORT SERVICES CONTRACT FOR FY 2017
DATE:	MAY 1, 2016

Recommendation
CPRIT staff recommends that the Oversight Committee provisionally approve a contract of $10 million for grant management support services at the May 18th Oversight Committee. This estimate is based on CPRIT's existing contract with a similar scope of services. The contract will be based on time and materials provided so CPRIT would only pay for actual services received from the vendor. The posted Request for Proposal (RFP) allows for four one-year renewal options which would bring the total value of the contract to approximately $50 million should they all be exercised.

As part of this provisional approval, CPRIT staff must present a summary of the proposed contract to the Audit Subcommittee at a to-be-scheduled mid-summer meeting. The Audit Subcommittee will review the proposed contract to confirm that it is consistent with the provisional approval from the Oversight Committee in May. After the Audit Subcommittee affirms consistency with the Oversight Committee decision, staff would be able to submit a request to the Legislative Budget Board (LBB) for approval of the contract more 45 days prior to the anticipated commencement of the contract on September 1, 2016, to be consistent with the 45-day timeframe required for approval by the LBB.

Note that if the Audit Subcommittee determines that the cost of the contract is inconsistent with the amount provisionally approved by the Oversight Committee, CPRIT will convene a special meeting of the Oversight Committee to approve the contract.

Background
CPRIT posted the RFP for end-to-end grant management support services that include grant application receipt, peer review evaluation, and post-award grants management on May 2, 2016. The RFP is open for 45 days.

Because the contract will exceed $10 million in value, CPRIT submitted the draft RFP to the interagency Contract Advisory Team Review and Delegation (CATRAD) for review in compliance with state law. CATRAD provided recommendations to the agency which are incorporated in the posted RFP and delegated authority to CPRIT to post the RFP and process proposals submitted in response to it.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	HEIDI MCCONNELL, CHIEF OPERATING OFFICER
SUBJECT:	FY 2017 REQUEST FOR FINANCING OF CPRIT BONDS
DATE:	MAY 9, 2016

Recommendation
CPRIT staff recommends that the Oversight Committee approve the attached resolution for a request for financing to the Texas Public Finance Authority (TPFA) to issue debt on behalf of CPRIT in fiscal year 2017. The amount to be financed is $300 million in bond proceeds appropriated to CPRIT for its operations and prevention and research grant awards. I estimate that CPRIT will request TPFA issue $233.4 million in commercial paper notes four times during fiscal year 2017 to pay for CPRIT administrative operations and grant reimbursements or authorized advances related to awards made in fiscal years 2011, 2012, 2013, 2014, 2015, 2016, and 2017.

The 2017 issuance estimate takes into account a number of grants awarded in 2011, 2012, and 2013 closing and also a higher number of grant awards that were declined in 2014 than anticipated.

Background
For fiscal year 2016, TPFA will issue $277.3 million by August 31, 2016, on CPRIT"s behalf. To date, TPFA has issued $69.8 million in commercial paper notes for CPRIT in this fiscal year to pay agency operations and grant payments.

In addition, TPFA has fixed out approximately $848.8 million in long-term general obligation bonds for debt CPRIT incurred in from fiscal year 2010 through fiscal year 2016.

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CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

A RESOLUTION
AUTHORIZING A REQUEST FOR FINANCING
AND THE EXECUTION AND DELIVERY OF DOCUMENTS
REQUIRED TO EFFECT SUCH FINANCING

Whereas, the Texas Public Finance Authority (the "Authority") is authorized to issue general obligation bonds to finance the grant program for cancer research and prevention and control for the use and benefit of the Cancer Prevention & Research Institute of Texas (the "Agency") pursuant to Article III, Section 67, Texas Constitution; Texas Health & Safety Code, Chapter 102, as amended; Texas Government Code, Chapter 1232, as amended; and provisions of the General Appropriations Act, 84th, Legislature, R.S. (2015), (collectively, the "Authorizing Law");

Whereas, the Agency desires and intends to request the Authority to finance the costs of the program as permitted by the Authorizing Law; and

Whereas, the Agency recognizes that in order to finance the cost of the program, the Authority may issue short term obligations, general obligation bonds, either or both ("Obligations") in an aggregate principal amount sufficient to finance program costs in the estimated amount of $300,000,000, plus the costs of issuance and related administrative costs, if any, which will be determined at the time of issuance; and

Whereas, the form of a Request for Financing, dated as of May 18, 2016, (the "Request for Financing") from the Agency to the Authority, which includes a detailed description of the program to be financed for the Agency ("program" herein) and a proposed expenditure schedule is presently before the CPRIT Oversight Committee.

NOW THEREFORE BE IT RESOLVED by the CPRIT Oversight Committee that:

Section 1. The purpose of the financing is to provide funds sufficient to make grant awards for cancer research and prevention and control and for the operations of the Agency, and the financing thereof is appropriate at this time. Accordingly, the execution and delivery of the Request for Financing to the Authority pursuant to the Authorizing Law is hereby ratified, approved and confirmed.

Section 2. The Chief Executive Officer of the Agency is hereby empowered, authorized and directed to:

a. sign and deliver any and all documents necessary or desirable to effect the financing and provide the projects, which may include but not be limited to a Memorandum of Understanding and a Financing Agreement between the Agency and the Authority;
b. cooperate with the Authority and its consultants to prepare an Official Statement in connection with the sale of the Obligations;
c. and to take any other action necessary to assist in such sale.

Section 3. All actions not inconsistent with provisions of this Resolution heretofore taken by the Institute and the Executive Director or designee thereof and the other officers of, or consultants to the Institute, directed toward the financing of the Program, and the issuance of the Obligations are hereby ratified, approved and confirmed.

Section 4. The officers and employees of the Agency shall take all action in conformity with the Authorizing Law to effect the issuance of the Obligations and complete the Program as provided in the Agreement and take all action necessary or desirable or in conformity with the Authorizing Law for carrying out, giving effect to, and consummating the transactions contemplated by the Memorandum of Understanding, the Agreement, the Obligations, and this Request for Financing, including without limitation, the execution and delivery of any closing documents in connection with the closing of the Obligations.

Section 5. This Resolution was adopted at a meeting open to the public, and public notice of the time, place and purpose of said meeting was given, all as required by Ch. 551, Texas Government Code.

Adopted by the affirmative vote of a majority of the Cancer Prevention and Research Institute of Texas Oversight Committee present and voting on this 18th day of May, 2016.

Cancer Prevention and Research Institute
of Texas Oversight Committee

Attested:

_____ _____

_____ _____

Chairman

Secretary

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

Fiscal Year 2017 Request for Financing Program Description

Purpose

The Cancer Prevention and Research Institute of Texas (CPRIT) is the state agency mandated to:

1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;
2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and
3) develop and implement the Texas Cancer Plan.

Powers and Duties

CPRIT will make grants to provide funds to public or private persons to implement the Texas Cancer Plan, and make grants to institutions of learning and to advanced medical research facilities and collaborations in this state for:

1) research into the causes of and cures for all types of cancer in humans;
2) facilities for use in research into the causes of and cures for cancer;
3) research, including translational research, to develop therapies, protocols, medical pharmaceuticals, or procedures for the cure or substantial mitigation of all types of cancer in humans; and
4) cancer prevention and control programs in this state to mitigate the incidence of all types of cancer in humans.

Implementation Plan

CPRIT estimates that $233.4 million in bonds proceeds must be issued on an as-needed basis consistent with Texas Government Code, Chapter 1232 to cover grant award obligations from fiscal years 2011, 2012, 2013, 2014, 2015, and 2016; new grant award obligations made during fiscal year 2017; and operating costs for general agency administration and pre- and post-award grants management processes. During fiscal year 2017, CPRIT will use the bond proceeds to disburse grant funds for grants awarded by CPRIT during the last three months of fiscal year 2011 as well as during fiscal years 2012, 2013, 2014, 2015, 2016, and 2017. CPRIT is currently authorized to obligate approximately $283 million for cancer prevention and research grant awards in fiscal year 2017.

CPRIT announces grant awards for cancer prevention education and service programs and academic and product development cancer research programs four times per year. CPRIT anticipates that it will obligate all of the available $283 million for cancer prevention, product development research, and academic research.

Grant funds are generally disbursed quarterly on a reimbursement basis to grant recipients. For certain types of grant awards, limited to product development, CPRIT advances funds in order to provide those specific types of recipients with working capital to meet their research milestones or objectives.

CPRIT is authorized to use bond proceeds to fund its grant review and award operations and indirect administration costs. At this time, the total budgeted amount of these two categories is $16.8 million in bond proceeds for fiscal year 2017 based on the authorized appropriations in General Appropriation Act, 84th Legislature. CPRIT must transfer $2.9 million in bond proceeds to the Texas Department of State Health Services (DSHS) for the operating costs associated with the Texas Cancer Registry. From the total of all of the agency's operating costs, CPRIT requires half of the proceeds to be available at the beginning of the state fiscal year to be able to cover the operating expenses for six months. CPRIT also requires proceeds at the beginning of each state fiscal quarter to pay for award costs reimbursed to grant recipients for the previous state fiscal quarter.

The scientific research program provides awards in the following areas: cancer biology, cancer genetics, immunology, imaging, therapeutics, prevention/epidemiology, and informatics/ computation. The product development research program focuses awards on the development of cancer drugs, diagnostics, and devices based on discoveries made in one of the seven areas described above. Prevention program grants are awarded for cancer prevention information and services, early detection and treatment, professional education and practice, cancer data acquisition and utilization, or survivorship (the areas of the Texas Cancer Plan). Awards for all programs are issued for multiple years, ranging from two to five years.

CPRIT has established a grant process that allows grant proposals for cancer prevention, scientific research, and product development research to be submitted through requests for applications (RFA) issued throughout each fiscal year. All proposals are reviewed by multiple experts in the appropriate area. CPRIT has approximately 200 national experts in cancer prevention, research and product development to review proposals and provide funding recommendations to CPRIT.

The award recommendations developed by the peer review committees are forwarded to the Program Integration Committee (PIC) for consideration. The five members of the PIC are statutorily defined as the Chief Executive Officer (CEO), Chief Scientific Officer, Chief Prevention Officer, Chief Product Development Officer, and DSHS Commissioner. The PIC finalizes award recommendations across all programs prior to every Oversight Committee meeting. When those proposed awards are forwarded to the Oversight Committee, each recommended award is accompanied by an affidavit signed by the CEO to affirm that the award followed all required pre-award grant procedures. The Oversight Committee considers these recommendations and votes to approve the awards.

Cancer Prevention and Research Institute of Texas

Estimated Expenditure Schedule, Fiscal Year 2017

Fiscal Year 2017	September	October	November	December	January	February	March	April	May	June	July	August	Total
Bond proceeds for Indirect Administration	$ 1,515,326	$ -	$ -	$ -	$ -	$ -	$ 1,515,326	$ -	$ -		$ -	$ -	$ 3,030,652
Bond proceeds for Grant Review and Award Operations	$ 6,905,113	$ -	$ -	$ -	$ -	$ -	$ 6,905,113	$ -	$ -	$ -	$ -	$ -	$ 13,810,226
Bond proceeds for Texas Cancer Registry (GAA 2016-17, Art. I, CPRIT Rider 5)	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 1,484,777	$ -	$ -	$ -	$ -	$ -	$ 2,969,554
Bond proceeds for Prevention and Research Grants	$ 57,694,784	$ -	$ -	$ 50,500,000	$ -	$ -	$ 49,794,784	$ -	$ -	$ 55,600,000	$ -	$ -	$ 213,589,568
Debt Issuance Subtotal, Fiscal Year 2016	$ 67,600,000	$ -	$ -	$ 50,500,000	$ -	$ -	$ 59,700,000	$ -	$ -	$ 55,600,000	$ -	$ -	$ 233,400,000
Cumulative Debt Total, Fiscal Year 2016	**$ 67,600,000**	**$ 67,600,000**	**$ 67,600,000**	**$ 118,100,000**	**$ 118,100,000**	**$ 118,100,000**	**$ 177,800,000**	**$ 177,800,000**	**$ 177,800,000**	**$ 233,400,000**	**$ 233,400,000**	**$ 233,400,000**	**$ 233,400,000**

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	CHIEF COMPLIANCE OFFICER REPORT
DATE:	MAY 5, 2016

The Chief Compliance Officer is responsible for apprising the Oversight Committee and the Chief Executive Officer of institutional compliance functions and activities. The required reporting includes quarterly updates to the Oversight Committee on CPRIT's compliance with applicable laws, rules, and agency policies (T.A.C. § 701.7). In addition, the compliance officer must inquire into and monitor the timely submission status of required grant recipient reports and notify the Oversight Committee and General Counsel of a grant recipient's failure to meaningfully comply with reporting deadlines.

Submission Status of Required Grant Recipient Reports

CPRIT grant compliance specialists monitor the status of grantee reports that are currently due. A summary of delinquent reports is produced by CPRIT's grant management system (CGMS) every week; this is the primary source used by CPRIT's compliance staff to follow up with grantees. CPRIT's grantees typically submit approximately 6,800 grantee reports throughout the year.

As of the end of April (CGMS report date April 22, 2016), 10 required grantee reports from 7 entities were not filed in the system by the set due date. In most cases, CPRIT does not disburse grant funds until the required reports are filed. In some instances, grantee institutions may be ineligible to receive a future award if required reports are not submitted. CPRIT's grant compliance specialists and grant accountants continue to review and process incoming reports and reach out to grantees to expeditiously resolve filing issues.

FSR Reviews

CPRIT's grant compliance specialists have performed 342 second-level reviews of grantee Financial Status Reports (FSRs) during this quarter, bringing the fiscal year total to over 1,300 second-level reviews. CPRIT's grant accounting staff completes the first review of the FSRs and supporting documentation before routing them to the compliance specialists for a second-level

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review. Of the 342 reviews completed by grant compliance specialists this quarter, only eight FSRs required resubmission (2.3%).

Annual Attestation (Self-Certification)

Grantees are required to submit an annual self-certification demonstrating compliance with statutory and administrative grant requirements, CPRIT's policies and procedures, the grant contract, and the Uniform Grant Management Standards (UGMS). This opportunity to self-report, in the form of a checklist, provides a baseline of grantee compliance and allows grant compliance specialists to proactively work with the grantee towards full compliance prior to a desk review or on-site review. All grantees are currently in compliance with the annual attestation standards.

Desk Reviews

Thirty-seven desk reviews have been performed so far this quarter, bringing the fiscal year total to 195 desk reviews performed. Desk-based financial monitoring/reviews are conducted during the course of grant awards to verify that grantees expend funds in compliance with specific grant requirements and guidelines. Desk reviews may target an organization's internal controls, procurement and contracting procedures and practices, current and past fiscal audits, subcontracting monitoring, and timeliness of required grantee report submission. Grant compliance specialists are actively working with 12 grantees to remediate desk review findings.

On-site Reviews

CPRIT compliance staff has performed three on-site reviews during the third quarter of FY2016; a total of 13 on-site reviews have been performed so far this fiscal year. On-site reviews may include examination of the grantee's financial and administrative operations, procurement and contracting policies and procedures, personnel policies and practices, payroll and timesheet policies, travel policies and records, and single audit compliance. No significant findings were identified during the on-site reviews.

Single Audit Tracking

As part of ongoing monitoring efforts, grant compliance specialists track the submission of grantees' independent audit reports and the resolution of issues identified in these reports. Grantees who expend $500,000 or more in CPRIT grant funds in the grantee's fiscal year must submit a single audit or have an audit performed according to an agreed upon procedures engagement. The findings must be compiled in an independent audit report and submitted to CPRIT within 30 days of receipt, but no later than 270 days after the recipient's fiscal year end.

There are currently no grantees with outstanding audit findings; however, grant compliance specialists are working with three grantees regarding delinquent audit reports. Grantees are unable to receive reimbursements or advances if they are delinquent in filing the required audit and corrective action plan, unless a request for additional time was submitted on or before the due date of the required audit and subsequently approved by CPRIT's CEO.

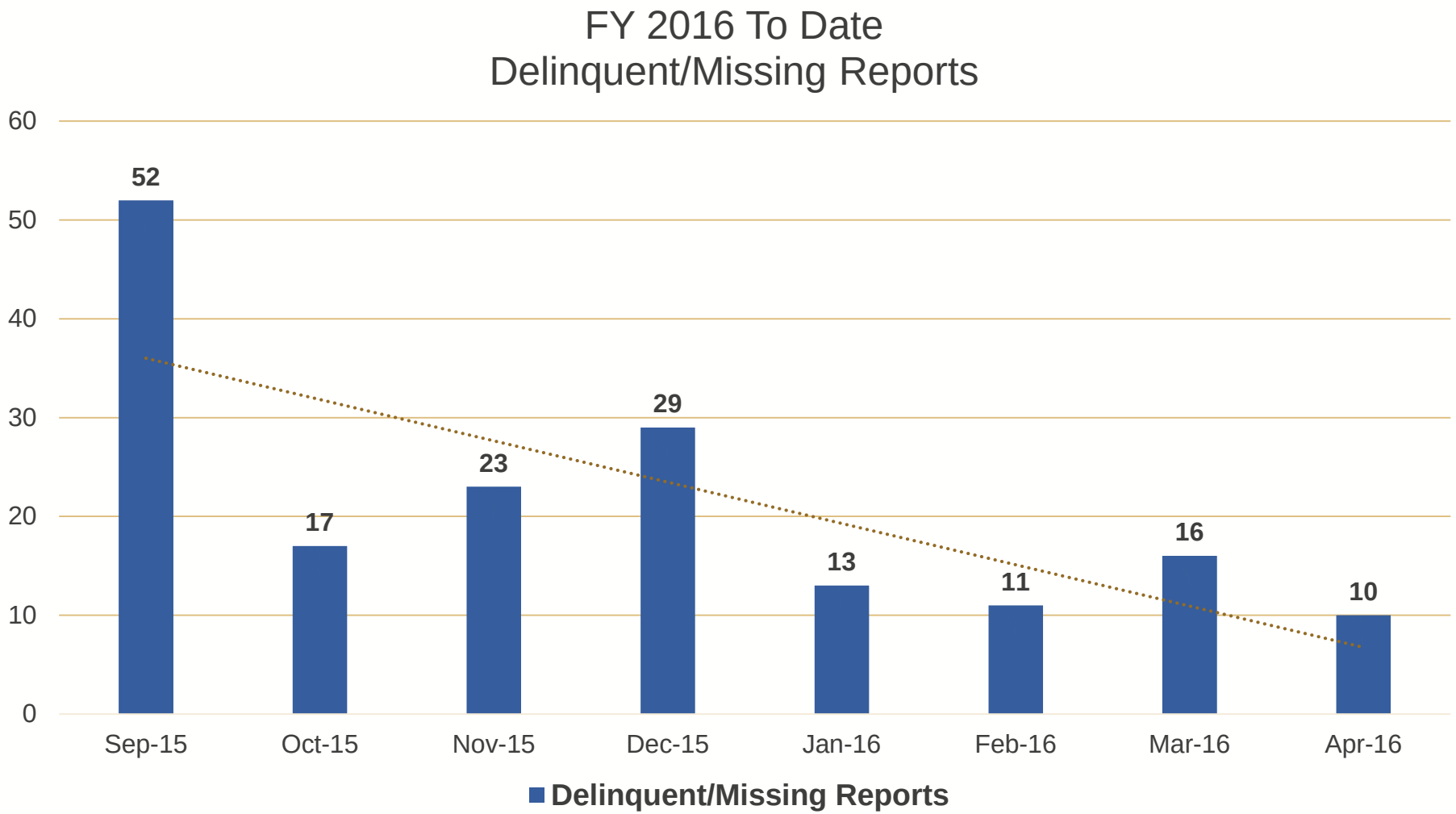
Training and Technical Assistance

CPRIT staff conducted a new grantee training for Coastal Bend Wellness Center in Corpus Christi on March 9. In addition to a brief overview of CPRIT's history and mission, the training covered grantee reporting requirements, an overview of the compliance program, and a hands-on navigation of CPRIT's online grants management system.

CPRIT staff conducted a grantee training webinar on March 30 for more than 300 grantee staff. The webinar focused on administrative rules changes, grantee reporting requirements, compliance program activities, and the grant closeout process. Grantees also had the opportunity to ask questions during the two-hour training webinar. The training outreach is part of CPRIT's efforts to address compliance issues early. Grantees that attended the webinar fulfilled the administrative rule requirement for annual compliance training. A second grantee training webinar is scheduled for June 15.

Also, CPRIT staff presented "Being a CPRIT Grantee: What You Need to Know" at the National Council of University Research Administrators (NCURA) Region V meeting in Dallas on April 25. The training covered grantee reporting requirements, an overview of the compliance program, a review of the most frequent compliance monitoring findings, and recent administrative rule changes.

Grant Recipient Report Monitoring



Reports Submitted: Approximately 6,800/Annually, Average 570/Monthly

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	VINCE BURGESS, CHIEF COMPLIANCE OFFICER
SUBJECT:	COMPLIANCE MONITORING SUPPORT SERVICES CONTRACT RENEWAL
DATE:	MAY 2, 2016

Recommendation

CPRIT staff would like to exercise the second one-year renewal option on the contract with CohnReznick for $500,800 to provide compliance monitoring support services in FY 2017. This contract will also require approval from the Legislative Budget Board before CPRIT will be able to execute it.

Background

CPRIT initially awarded CohnReznick the contract in FY 2015. CPRIT exercised the first one-year renewal option in FY 2016. This contract allows CPRIT to augment the agency's in-house compliance staff to perform desk reviews and on-site monitoring reviews of CPRIT grant recipients. In CPRIT's FY 2017 compliance monitoring plan, CohnReznick will perform approximately 100 desk reviews and 30 on-site monitoring reviews of grant recipients. CohnReznick also supports the annual risk assessment process and development of the annual grant compliance monitoring plan.

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Third Quarter 2016 Oversight Committee
Internal Audit Status Report

Weaver and Tidwell, LLP (Weaver) was engaged to provide outsourced internal audit services to Cancer Prevention Research Institute of Texas (CPRIT). The Weaver engagement team is led by Alyssa Martin, Partner; Daniel Graves, Sr. Manager; and Adam Wright, Manager.

Weaver met with CPRIT Management to review the approved 2016 Internal Audit Plan prepared from the results of the 2015 Internal Audit Risk Assessment.

2016 Internal Audit Plan

Internal Audit	Description	Planned Timing
Planned 2016 Internal Audits		
Commodity and Service Contracts	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Commodity and Service Contracts practices. Activities to be evaluated will include Contract Compliance, Contract Management and Professional Services. The audit team is currently in the field.	May 2 – May 18
Revenue	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Revenue practices. Activities to be evaluated will include General Obligation Bonds, License Plate Fees, Application Fees, Revenue Sharing and Other Revenue Sources.	June 20 – July 1
Information Security	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Information Security practices. Activities to be evaluated will include Internal and External Security, Logical Access, Physical Access, Risk Assessment, and Compliance with security and privacy requirements.	July 11 – July 22
Cash Management	Internal Audit will include an evaluation of risks and internal controls in place related to CPRIT's Cash Management practices. Activities to be evaluated will include Electronic Funds Transfer Processing, State Treasury Reconciliations and Cash Forecasting.	July 25 – August 5

Internal Audit	Description	Planned Timing
Planned 2016 Follow-Up Procedures of Prior Audit Findings		
Information Technology Services • 1 Moderate Finding • 1 Low Finding	Internal Audit will perform follow-up procedures on 2015 Internal Audit findings to verify management's reported status and completion of corrective actions taken to resolve prior internal audit findings.	May 30 – June 3
Pre-Award Grant Management Post-Award Grant Management Grant Contracting • 8 Moderate Findings • 1 Low Finding		June 1 – June 10
2016 Annual Internal Audit Requirements		
Project Management	Coordinating internal audit activities with Management, tracking status of audit plan and reporting to Management.	Ongoing
Risk Assessment Update	Annual update of the internal audit risk assessment.	Late August
Annual and Quarterly Oversight Committee Reports	Preparation and submission of the required Annual Internal Audit Report and quarterly reports to the Audit Subcommittee and Oversight Committee of internal audit activities.	Ongoing

Weaver reported the status of the 2016 Internal Audit Plan to the Audit Subcommittee on May 9, 2016.

Alyssa G. Martin, CPA, MBA, Internal Auditor
Executive Partner
Weaver and Tidwell L.L.P

Cancer Prevention and Research Institute of Texas
Commodity and Service Contracts Internal Audit
Internal Audit Risk Coverage
May 2016

Scope: The audit will focus on the Commodity and Service Contracts processes in place at the Cancer Prevention Research Institute of Texas. We will review the procedures for appropriate risk and regulatory coverage and compliance. Key functions and sub-processes within the Commodity and Service Contracts process to be reviewed will include:

- Contract Initiation and Execution
- Contract Management
- Contract Close-out

The audit will evaluate only non-grant contracts and will not include an evaluation of the procurement process.

Monitored Risks

Commodity and Service Contracts		
Process Area	**Risks Monitored**	
Process-Wide	**1**	Policies and procedure are not in place to ensure that inconsistencies or errors are identified in the authorization, processing, and monitoring of contracts
	2	Appropriate segregation of duties do not exist in the review, approval, execution, and monitoring of contracts
Contract Initiation and Execution	**3**	Vendors whose goods or services require contracts are not appropriately identified
	4	Standard contract terms and conditions are not identified and documented
	5	Contract elements are not in compliance with State requirements
	6	Contract modifications are not properly reviewed and approved
	7	Contracts are not properly authorized and executed by appropriate individuals
	8	Contracts exceeding oversight thresholds are not appropriately approved
	9	Usage of cooperative contracts are not appropriately reported
	10	Vendors are not properly on-boarded
Contract Management	**11**	Contract obligations are not accurately computed
	12	Contract invoices are not reviewed for compliance with contract terms
	13	Contract budgets are not monitored
	14	Changes, modifications, and/or amendments to existing contracts are not appropriately addressed by authorized individuals
	15	Contracts that are set to renew are not renewed timely and appropriately
	16	Contract performance is not monitored or managed to ensure timely delivery of services, compliance with contract terms, and performed as agreed
	17	Vendor performance evaluations are not performed in accordance with State statutes
	18	Program Managers do not have adequate training to comply with vendor evaluation and reporting requirements
Contract Close-out	**19**	Contracts that are expired or become obsolete are not identified
	20	Contracts are not adequately closed for subsequent monitoring and reporting

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	NED HOLMES, CHAIR, BOARD GOVERNANCE SUBCOMMITTEE
SUBJECT:	INTENTION TO RECOMMEND APPROVAL OF FINAL ORDER ADOPTING ADMINISTRATIVE RULES CHANGES
DATE:	MAY 5, 2016

Recommendation

The Board Governance Subcommittee recommends that the Oversight Committee vote to approve final orders adopting changes to T.A.C. §§ 702.11, 703.12, and 703.21.

Discussion

The Oversight Committee preliminarily approved three rule changes at its February 2016 meeting. The proposed rule changes affect professional conflicts of interest, the limitation on the use of grantee funds, and financial status report (FSR) reimbursement waivers. After publishing the proposed changes in the *Texas Register*, CPRIT received comments from one institution regarding the proposed changes to § 703.21.

The Board Governance Subcommittee reviewed the comments and final orders with CPRIT's General Counsel at its meeting on May 5, 2016. The Board Governance Subcommittee recommends the Oversight Committee approve the final orders adopting the proposed rule changes.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	KRISTEN PAULING DOYLE, GENERAL COUNSEL CAMERON L. ECKEL, STAFF ATTORNEY
SUBJECT:	SUMMARY OF PROPOSED RULE CHANGES TO BE ADOPTED
DATE:	MAY 5, 2016

Summary

The proposed administrative rule changes to Chapters 702 and 703, originally considered by the Oversight Committee in February 2016, are ready for final adoption. CPRIT received comments from one grantee institution regarding the proposed changes after publication of the rule changes in the *Texas Register*. CPRIT legal staff recommends that the Oversight Committee adopt the rule changes as originally proposed. Once the Oversight Committee approves the final orders, CPRIT will submit the rule changes to the Secretary of State and the changes will be considered final and effective 20 days later.

Discussion

CPRIT's administrative rules set policy guiding CPRIT's grant review and grant contracting processes. State law requires agencies to set policy using the rulemaking process, which includes an opportunity for the public to comment on proposed rules and rule changes before the agency adopts the final policy. The proposed rule changes preliminarily approved by the Oversight Committee in February make the following three changes to the agency's administrative rules:

- Rule § 702.11 "Conflicts of Interest Requiring Recusal" - The proposed amendment clarifies that serving as a consultant or contractor for a grant applicant constitutes a professional conflict of interest. This additional description fills a gap that currently exists.

- Rule § 703.12(b)(1) "Limitation on Use of Funds" – The change adds visa fees to the expenses that are not authorized to be reimbursed by CPRIT grant funds.

- Rule § 703.21(b)(2) – The amendment adds an appeal process if a grantee's reimbursement of project expenses is waived by CPRIT. A grantee waives reimbursement for otherwise allowable expenses incurred in a fiscal quarter if the grantee

fails to submit a financial status report within 120 days after the end of the fiscal quarter. The proposed process allows the grantee to appeal the waiver of reimbursement. The grantee's appeal must be in writing and submitted to the CEO through CPRIT's electronic grant management system. The CEO's decision to approve the appeal and reverse the waiver is final. However, after discussion with the Board Governance subcommittee, the proposed rule reflects the grantee's option to seek reconsideration from the Oversight Committee if the CEO denies the grantee's appeal. The grantee must submit a written request to the CEO within 10 days. If at least three Oversight Committee members agree, the Oversight Committee will consider the grantee's appeal at an open meeting. The Oversight Committee's decision is final.

CPRIT published the proposed rules in the March 4 and March 25 editions of the *Texas Register*, as well as solicited public comment via CPRIT's website. CPRIT received one comment regarding the proposed change to § 703.21 from The University of Texas at Dallas (UTD). UTD did not disagree with the proposed change but requested more information on the process to appeal the waiver of a grantee's right to reimbursement of project costs, including information on the appropriate tab to use to submit the request through CPRIT's electronic grant management system.

I do not recommend changes to the proposed rule in response to UTD's comments. While state law requires agencies to adopt policies through the rulemaking process, purely informational guidance is not required to be included in administrative rules. In this case, providing the option for a grantee to appeal the waiver of its right to reimbursement when it fails to submit the required report by the specified deadline qualifies as a CPRIT policy decision requiring approval via the rulemaking process. On the other hand, instructions regarding the appropriate electronic tab to use to submit the appeal via CPRIT's grant management system is not a policy decision and does not need to be formally ratified by the rulemaking process. Adding this level of specificity to administrative rules also makes it difficult to change the rule quickly if CPRIT alters the format of its tabs. CPRIT will provide the guidance requested by UTD through instructions in CPRIT's electronic grant management system.

Next Steps

After the Oversight Committee adopts the proposed rule changes, CPRIT will submit the final orders to the Secretary of State. The rule changes become effective 20 days after the date CPRIT files the orders with the Secretary of State.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 702. Institute Standards on Ethics and Conflicts, Including the Acceptance of Gifts and Donations to the Institute

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to § 702.11 regarding professional conflicts of interest. The proposed amendments were published in the March 4, 2016, issue of the *Texas Register* (41 TexReg 1648).

Reasoned Justification

The proposed to change to § 702.11 clarifies that a professional conflict of interest includes serving as a consultant or contractor to a grant applicant. It also expands the applicability of the rule to include the time that the individual is actively seeking to represent a grant applicant. Finally, the proposed amendment provides examples of activities that constitute "actively seeking to represent" such that the rule is invoked.

Summary of Public Comments and Staff Recommendation

No public comments germane to the proposed rule amendment were received.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on May 23, 2016.

TITLE 25. HEALTH SERVICES

PART 11. CANCER PREVENTION AND RESEARCH INSTITUTE OF TEXAS

CHAPTER 703. Grants for Cancer Prevention and Research

The Cancer Prevention and Research Institute of Texas ("CPRIT" or "the Institute") adopts the amendments to §§ 703.12 and 703.21 regarding unallowable grantee expenses and the process to appeal a waiver of reimbursement of project costs. The proposed amendments were published in the March 25, 2016, issue of the *Texas Register* (41 TexReg 2302).

Reasoned Justification

The proposed to change to § 703.12 specifies that fees and expenses associated with acquiring or maintaining a visa are not authorized expenses to be paid with grant funds. The proposed change to § 703.21 adds an appeal process if a grantee's reimbursement of project expenses is waived by CPRIT. Project costs are waived when a grantee fails to submit a financial status report within the required timeframe.

Summary of Public Comments and Staff Recommendation

CPRIT received one comment regarding the proposed change to § 703.21 from The University of Texas at Dallas (UTD). UTD did not disagree with the proposed change but requested more information on the process to appeal the waiver of a grantee's right to reimbursement of project costs, including information on the appropriate tab to use to submit the request through CPRIT's electronic grant management system.

CPRIT declines to make a change to the rule as originally proposed. Information requested by the commenter is ministerial. CPRIT will provide instructions to grantees regarding how to submit and document an appeal. The submittal process instructions will not alter the policy behind the proposed rule change.

The rule changes are adopted under the authority of the Texas Health and Safety Code Annotated, §§ 102.108 and 102.251, which provides the Institute with broad rule-making authority to administer the chapter, including rules for awarding grants.

Certification

The Institute hereby certifies that the adoption has been reviewed by legal counsel and found to be a valid exercise of the agency's legal authority.

To be filed with the Office of Secretary of State on May 23, 2016.

CANCER PREVENTION & RESEARCH
INSTITUTE OF TEXAS

MEMORANDUM

TO:	OVERSIGHT COMMITTEE MEMBERS
FROM:	CYNTHIA MULROW, M.D., CHAIR, DIVERSITY SUBCOMMITTEE
SUBJECT:	DIVERSITY SUBCOMMITTEE REPORT
DATE:	MAY 10, 2016

Summary:
The Oversight Committee' s Subcommittee on Diversity met on May 6, 2016, and discussed CPRIT's Historically Underutilized Businesses (HUB) Report and Changes in the 2016-17 state budget HUB reporting requirements, grant recipient data collection related to diversity issues and transferring the responsibilities of the subcommittee to other subcommittees. This latter point results by considering that diversity issues are an important aspect of CPRIT's mandate that deserve integration into all programs rather being handled by a separate subcommittee. The Diversity Subcommittee requests comments about a transfer be provided for the Subcommittee's consideration at its August 2016 meeting.

Discussion:
The Diversity Subcommittee has not met since February 6, 2015, due to lack of a quorum (August 7, 2015) and for two quarters while awaiting new chief scientific and chief product development officers. Chief Executive Officer Wayne Roberts recommended delaying these latter two meetings since research and prevention topics need input from all of the programmatic officers.

The meeting on May 6 consisted of revisiting issues under consideration by the subcommittee at the point of its hiatus, updates on agency activities related to diversity and discussion of future directions of the subcommittee.

Historically Underutilized Businesses (HUB) Report
Heidi McConnell, Chief Operating Officer, and Don Brandy, Purchaser, presented the agency's FY 2016 Historically Underutilized Business Plan (Attachment 1). This information was submitted to the Legislative Budget Board and Comptroller in November 2015 and is subject to audit by the State Auditor. This plan includes an analysis of HUB data for the prior two years required by Article IX provisions of the General Appropriations Act for the 2016-17 biennium. CPRIT expenditures per certified HUB group improved from FY 2014 to FY 2015 with respect to expenditures per Asian Pacific, Black, and Hispanic categories but declined for the Women

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category. The dollars involved are small and pertain only to agency administrative expenditures. For the agency as a whole, HUB expenditures remain small (1.95 percent) due to the size of the approximately $10 million per year grant management support services contract with SRA International. During Mr. Brandy's tenure at the agency, CPRIT's HUB outreach has increased significantly due to his attendance at HUB events, such as small business trainings and forums, where he distributes information about the agency and its procurement needs to HUB vendors. In addition, Mr. Brandy gains knowledge about certified HUB vendors at these events who perform services or provide commodities needed by CPRIT.

CPRIT Data Collection Related to Diversity Issues

Dr. Willson, Chief Scientific Officer, in preparation for the subcommittee meeting had requested diversity metrics concerning academic research grants which were provided to the subcommittee (Attachment 2). Ethnicity and racial characteristics are not required information for principal investigators though voluntary reporting is requested. As of April 8, 2016, 82.2 percent of grantees provided race and ethnicity information. At this time the subcommittee advises continued voluntary reporting of racial and ethnic information.

Diversity issues are complicated by many factors but their importance are recognized by health science centers, universities, the National Institutes of Health, and the National Cancer Institute. CPRIT has anecdotal information that its Academic Research Training Grants have had a positive impact in attracting individuals from historically underrepresented groups in science and medicine. However, hard metrics have not been reported to CPRIT that could be used in quantifying these programs' effectiveness. For training grants, data on who is being trained, their retention in scientific fields beyond the program and their advancement are unavailable at this time. Data for individuals in clinical trials are also unreliable for a variety of reasons, including Health Insurance Portability and Accountability Act (HIPAA) privacy requirements. HIPAA has proven to be a barrier to CPRIT in collecting data in discrete geographic areas, e.g., legislator districts.

Transferring the Responsibilities of the Diversity Subcommittee to Other Standing Subcommittees

CPRIT staff requested that the Diversity Subcommittee consider recommending to the Oversight Committee that its charges be transferred to the Academic Research, Product Development Research, Prevention and Audit Subcommittees. The subcommittee members attending the meeting recommend that this action be considered. Diversity issues are important and could be considered by all OC members through their participation on one or more of the three main program subcommittees. These issues include increasing participation by individuals from groups historically underrepresented in science and medicine, geographic and population services and dispersion of awards, agency employment practices and state mandated HUB vending requirements. Issues of increasing participation by individuals from groups historically

underrepresented in science and medicine are perhaps best addressed through the three program subcommittees. HUB purchasing efforts and the diversity of agency personnel are perhaps best addressed with the agency operating budget and procurement issues already considered by the Audit Subcommittee. The subcommittee recommends that each member of the Oversight Committee consider transferring the Diversity Subcommittee's responsibilities to the four subcommittees referenced above. Feedback is requested for the Diversity Subcommittee's consideration at its August meeting.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

FY 2016 Historically Underutilized Business Plan

Historically Underutilized Businesses (HUB) Program

The HUB program is governed by the Texas Government Code, Title 10, Subtitle D, Chapter 2161 and rules established by the Comptroller of Public Accounts' Texas Procurement and Support Services Division (TPASS) in Texas Administrative Code, Title 34, Part 1, Chapter 20, Subchapter B. The purpose of the program is to increase contracting opportunities with the State of Texas for minority-owned, veteran-owned, and women-owned businesses.

The goal of CPRIT's HUB program is to make a good faith effort to award procurement opportunities to certified HUB vendors. CPRIT purchases are historically in three primary procurement categories including Professional, Other Services, and Commodity Purchasing. Certified HUB vendors are classified under an object code that allows TPASS to track the agency's HUB expenditures through the Uniform Statewide Accounting System.

As a small agency with 32 full-time equivalents (FTE), CPRIT has one FTE dedicated to purchasing, not a purchasing department. The purchaser's duties include the role of HUB Coordinator and the responsibility to ensure that the agency implements the HUB outreach and procurement strategies identified in this report to increase HUB utilization.

CPRIT depends on TPASS to manage the HUB certification process for vendors and maintain the categorical lists of HUB vendors who can provide services and commodities to state agencies. CPRIT also depends on the Department of Information Resources to maintain an adequate number of information technology contracts with certified HUB vendors. CPRIT's primary contact with certified HUB vendors occurs when the agency procures services or commodities. Therefore, CPRIT does not have the capability to analyze and address statistical disparities by race, ethnicity and gender classification in current HUB utilization; statistical disparities by race ethnicity and gender classification in the private marketplace, particularly in commercial construction; and statistical disparities in firm earnings by race, ethnicity and gender classification. Nor does CPRIT have the capability to gather anecdotal testimony of disparate treatment from business owners.

HUB Participation

CPRIT is continuously implementing strategies to increase the agency's HUB participation and to ensure the agency complies in fact and spirit with the laws and rules established for the HUB

program. This compliance includes adherence to HUB planning and reporting requirements and to HUB purchasing procedures established by TPASS. As part of the effort to increase HUB participation, the purchaser must ensure that procurement opportunities are distributed among HUB groups, not concentrated within one or two HUB groups.

The strategies the agency uses to increase utilization of HUB vendors through its procurement processes for all goods and services and outreach activities are:

- Utilizing the TPASS Centralized Master Bidders List (CMBL) and HUB search to ensure that all eligible certified HUBs are notified of CPRIT's procurement opportunities;
- Utilizing HUB resellers from the Department of Information Resources' information technology contracts as often as possible;
- Attending HUB Workgroup Discussion meetings;
- Attending HUB small business trainings and HUB forums to increase awareness of CPRIT procurement opportunities among HUB vendors; and
- Participating in available meetings with HUB vendors at other agencies.

Assessment on Utilization of HUB Vendors

CPRIT uses the statewide annual HUB procurement goals as the agency goals. Based on those goals, CPRIT exceeded the annual procurement goal in the Special Trade and Commodity Purchasing categories.

FY 2015 HUB Expenditures

Procurement Category	Total Expenditures	Total Spent with HUBs ($)	Total Spent with HUBs (%)	Annual Procurement Goal
Special Trade	$33,378	$14,910	44.67%	32.90%
Professional	$320,519	$14,226	4.44%	23.70%
Other Services	$11,608,568	$158,150	1.36%	26.00%
Commodity Purchasing	$103,567	$47,812	46.17%	21.10%
Total	**$11,830,933**	**$235,099**	**1.95%**	

*CPRIT does not make purchases in Heavy Construction and Building, so those procurement categories are not included in the table.

FY 2014 HUB Expenditures

Procurement Category	Total Expenditures	Total Spent with HUBs ($)	Total Spent with HUBs (%)	Annual Procurement Goal
Special Trade	$382	$0	0%	32.70%
Professional	$331,865	$35,800	10.79%	23.60%
Other Services	$9,656,472	$9,471,936	1.91%	24.60%
Commodity Purchasing	$42,791	$31,005	27.54%	21.00%
Total	**$9,799,390**	**$232,122**	2.31%	

*CPRIT does not make purchases in Heavy Construction and Building, so those procurement categories are not included in the table.

Compared to fiscal year 2014, CPRIT purchases from HUB vendors increased significantly in both categories in actual dollars spent and in the percentage of spending in fiscal year 2015. In fiscal year 2014, CPRIT made no purchases from HUB vendors in the Special Trade category while Commodity Purchasing spending was $11,786 or 27.54 percent among HUB vendors. The increased spending in the Special Trade category can be attributed to one-time capital expenses related to construction of its new office space in the state-owned William B. Travis Building. CPRIT moved into its new office space in February 2015, so spending in this category is not expected to recur in future years. However, it does appear that the purchaser's efforts as described in the strategies outlined above have resulted in an increase in the agency's spending by $36,026 or 18.63 percent with HUB vendors in Commodity Purchasing.

However, CPRIT had low HUB purchasing percentages in Professional and Other Services. Professional Services is composed of accounting and auditing firm services that CPRIT must procure to meet the requirements of state law for internal audit, an independent financial audit and grant compliance monitoring. In both fiscal years 2014 and 2015, CPRIT procured independent financial audit services from a certified HUB vendor. CPRIT has not been able to procure services for its other needs in this category given the limited number of certified HUB vendors who provide these services.

The bulk of CPRIT purchases fall into Other Services. In fiscal year 2015, CPRIT made $11.6 million worth or 98 percent of agency purchases in this category. CPRIT also made 98 percent of its purchases in this category in fiscal year 2014. Agency purchases in this Other Services category include major contracts for specialized services like pre- and post-award grant management support services for CPRIT's grant programs, outside counsel services for intellectual property due diligence on CPRIT product development research grant applications, business and regulatory due diligence on CPRIT product development research grant applications, third-party peer review meeting monitoring services, and an annual economic assessment of the cost of cancer in Texas. In fiscal year 2015, this category also included a one-time expense for moving services. For the specialized services that CPRIT must procure to fulfill its mission, there are very few vendors who provide many of these services. For pre- and post-award grant management support services and business and regulatory due diligence, CPRIT has not received proposals from vendors in Texas who can provide these services nor is aware of any vendors in Texas who can provide these service. The same is true for business and regulatory due diligence services. Therefore, there is a corresponding lack of certified HUB vendors who can provide these services. This category also includes CPRIT's expenditures for honoraria payments to the chairs of its peer review committees which evaluate the hundreds of cancer prevention and research grant applications CPRIT receives each year. The chairs of CPRIT's peer review committees are recruited for their recognized expertise in a cancer research field and must live outside the state due to conflict of interest issues with potential grant applicants, so no alternatives exist to procure similar services from certified HUB vendors.

During fiscal year 2015, CPRIT continued to purchase from four of the six procurement categories and conducted business or awarded contracts to four of the six HUB groups. CPRIT does not anticipate that it will purchase from businesses in additional procurement categories since it does not engage in purchases in the Heavy Construction or Building categories. In fact, CPRIT anticipates that purchases from businesses in the Special Trade procurement category will decline to no purchases in fiscal year 2016.

FY 2015 Expenditures by Certified HUB Group

Certified HUB Group	Total Number of HUB Vendor(s) Receiving Contract Awards	Percent of HUB Vendors Receiving Awards	Total Dollars Awarded to HUB Groups	Percent of Total Dollars Awarded to HUB Groups
Asian Pacific	1	11.11%	$27,485	11.63%
Black	3	33.33%	$47,587	20.24%
Hispanic	1	11.11%	$7,625	3.24%
Native American	0	0.00%	$0	0.00%
Service-Disabled Veteran	0	0.00%	$0	0.00%
Women	4	44.44%	$152,401	64.82%
Total	**9**	**100.00%**	**$235,099**	**100.00%**

FY 2014 Expenditures by Certified HUB Group

Certified HUB Group	Total Number of HUB Vendor(s) Receiving Contract Awards	Percent of HUB Vendors Receiving Awards	Total Dollars Awarded to HUB Groups	Percent of Total Dollars Awarded to HUB Groups
Asian Pacific	0	0.00%	$0	0.00%
Black	1	12.50%	$35,800	15.42%
Hispanic	0	0.00%	$0	0.00%
Native American	0	0.00%	$0	0.00%
Service-Disabled Veteran	0	0.00%	$0	0.00%
Women	7	87.50%	$196,322	84.58%
Total	**8**	**100.00%**	**$232,122**	**100.00%**

The total amount spent by CPRIT among certified HUB vendors remained relatively constant between fiscal years 2014 and 2015. Although its overall spending with HUB vendors did not change, CPRIT increased the diversity of its spending among four of the six different HUB groups in fiscal year 2015 compared to two HUB groups in fiscal year 2014. During fiscal year 2016, the agency will make a good faith to maintain this diversity and improve upon it with a concentrated effort to conduct business with the two HUB groups, Service-Disabled Veteran and Native American, with which the agency did not conduct business during fiscal year 2015. CPRIT will accomplish this by continued attendance at statewide HUB events and actively

seeking out the group codes on the CMBL and DIR contract list to make these vendors aware of CPRIT purchasing opportunities.

HUB Outreach

CPRIT's HUB outreach efforts have two purposes. One is to distribute information about the agency and its procurement needs to HUB vendors at HUB events, such as small business trainings and forums. The other is for the purchaser to gain knowledge about certified HUB vendors who perform services or provide commodities needed by the agency. During fiscal year 2015, CPRIT's purchaser participated in several HUB events.

HUB Events Attended in FY 2015

HUB Event Name	Location	Date of Event
University of Houston 2015 Vendor HUB Fair	Houston	April 15, 2015
Senator West's Doing Business Texas Style	Irving	May 11-12, 2015
2015 Procurement Connection Seminar & Expo	Austin	August 29, 2015

In fiscal year 2016, CPRIT's purchaser plans to participate in the scheduled HUB events outlined below. The purchaser will add other activities as other HUB events are scheduled throughout the year.

HUB Events Planned in FY 2016

HUB Event Name	Location	Date
University of Houston 2016 Vendor HUB Fair	Houston	April 2016
Senator West's Doing Business Texas Style	Irving	May 2016
2016 Procurement Connection Seminar & Expo	Austin	August 2016

CPRIT's outreach efforts include responding to all email and hard copy communication received from HUB vendors, including vendors met at HUB events. Through these efforts CPRIT has established new relationships with HUB vendors and re-established relationships with other HUB vendors that the purchaser had at other state agencies.

CPRIT's Outreach effort at HUB events also includes providing agency information and literature on grant funding opportunities to HUB vendors specializing in providing cancer screening and prevention awareness to their local communities.

Attachment 2

PI/PD/CR Race/Ethnicity Data - CGMS Grants (982) as of 4/8/2016		
Race/Ethnicity of PI/PD/CR	Count	% of Respondents
American Indian/Alaska Native	5	0.6%
Asian	244	30.2%
Black or African American	27	3.3%
Hispanic or Latino	62	7.7%
Native Hawaiian or Pacific Islander	0	0.0%
Other	1	0.1%
White	458	56.8%
Asian and African American	1	0.1%
Asian, African American, Hispanic, and White	4	0.5%
American Indian and African American	1	0.1%
American Indian and White	4	0.5%
TOTAL Respondents	807	100.0%

175 of 982 (17.8%) gave no response